

National Liver Review Board (NLRB)

Frequently Asked Questions

Implementation

I thought the NLRB was being implemented on January 31, 2019? What happened?

During the time between NLRB implementation and the implementation of the new liver distribution policy, the primary geographic unit of liver allocation will still be the local donation service area (DSA). When the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (Liver Committee) reviewed the median model for end-stage liver disease (MELD) at transplant (MMaT) scores using a calculation based on a 250 nautical mile (NM) circle (MMaT/250) around each transplant program, they noticed that some transplant programs in the same DSA had different MMaT scores. This meant that candidates at these programs would appear lower on each match run and would be disadvantaged until the new liver distribution policy goes into effect. Once this issue was realized, the Liver Committee and the OPTN/UNOS Executive Committee proposed assigning a MMaT score for each transplant program based on the DSA (MMaT/DSA) during the transitional period between the implementation of the NLRB and the new liver distribution system.

This [proposal](#) was put out for public comment on January 31, 2019 and it will be open until March 22, 2019. At that point, the Liver and Executive Committees will consider the input received and decide on a path forward.

We invite all interested parties to read and comment on all parts of the proposal. In addition, because NLRB policy may change as a result of public feedback, the following information is considered to be pending and is subject to change.

When will the NLRB be implemented?

If the public comment proposal is supported in public comment and approved by the OPTN/UNOS Board of Directors (the Board), the NLRB is expected to be implemented around March 31, 2019.

When will the new distribution system be implemented?

The new liver distribution system is slated to go into effect on April 30, 2019.

Transition

How is the NLRB different than the Regional Review Boards (RRB)?

Regional review boards were comprised of review board members from within the region, and provided exception scores based on regional agreements and their understanding of the medical need of the patient. The review board in each region reviewed every exception application in that region.

The NLRB is divided by specialty (Adult HCC, Pediatrics, and Adult Other Diagnoses) and each review board is comprised of members from across the country. The goal of the NLRB is to remove regional differences in exception scoring and provide fair, equitable, and prompt peer review of exception candidates.

How is exception scoring changing with the implementation of the NLRB?

OPTN Policy 9.5: *Specific Standardized MELD or PELD Score Exceptions* defines the medical criteria for nine diagnoses awarded standard exception scores and outlines the score a candidate will receive when these criteria are met. The scores awarded for the standard diagnoses will change with the implementation of the NLRB. Rather than being awarded a set score, most of the diagnoses receive a policy assigned score (PAS) that is based on the MMaT score of the transplant program at which the candidate is listed. PELD candidates will receive a score relative to the median pediatric end-stage liver disease (PELD) at transplant (MPaT) across the nation. Refer to [OPTN/UNOS Policy 9.5 in the NLRB policy language](#) for full details on score assignments and qualifying medical criteria.

<u>Diagnosis</u>	<u>18 years or older at time of registration</u>	<u>At least 12 years old and less than 18 years old at time of registration</u>	<u>Less than 12 years old</u>
Hepatic Artery Thrombosis (HAT)	MELD 40	No standard score	No standard score
Hepatocellular Carcinoma (HCC)	MMaT -3 upon 2 nd extension	MELD 40	PELD 40
Cholangiocarcinoma (CCA)	MMaT -3	MMaT	MPaT
Cystic Fibrosis	MMaT-3	MMaT	MPaT
Familial Amyloid Polyneuropathy (FAP)	MMaT-3	MMaT	MPaT
Hepatopulmonary Syndrome (HPS)	MMaT -3	MMaT	MPaT
Metabolic Disease	No standard score	MMaT	MPaT
Portopulmonary Hypertension	MMaT -3	MMaT	MPaT
Primary Hyperoxaluria	MMaT	MMaT +3	MPaT +3

How do I handle the transition for candidates who already have an exception? Do I need to reapply?

For candidates with an existing exception at the time of the NLRB implementation, their exception score will stay the same until that exception is due to expire. Exception scores must still be renewed on a periodic basis, and the new criteria (and any resulting new score) would apply at the time of renewal. Exceptions and extensions filed after implementation will be valid for 90 days. This is a change from the previous exception period of 3 months.

If the transition proposal that is currently posted for [public comment](#) is approved, the candidates who apply for an extension or a new exception during the transitional period will receive a score relative to MMaT/DSA. These candidates will then have their scores converted to a MMaT/250-based score when the new allocation system is implemented. However, because the transition

period will only be one month, there will be candidates with an existing exception who are not due for an extension during this time period. Candidates who apply for an extension or new exception after the new allocation system is implemented will be awarded a score relative to MMaT/250.

It is worth noting that some candidates may receive a higher MELD or PELD score under the new policy. Transplant programs may choose to apply for a new exception early for those candidates, so that they can have the higher MELD or PELD score as soon as possible.

Will patients who have a MELD score of 28 or greater be grandfathered in at the time of transition?

There will not be any grandfathering. Candidates with existing exceptions at the time of implementation will keep their current score until it is time for their next extension. Upon approval of the extension, their score will shift to the MMaT-based score.

Education for Patients

What will this change mean for my patients?

Your patient's MELD or PELD exception score could change. Depending on their current MELD or PELD score and the MMaT or MPaT for your transplant program, each patient's score may change as a result of the new policy. Scores for existing exception patients will not change until they apply for an extension after implementation.

Patients that are utilizing their calculated MELD or PELD scores for allocation could have more opportunities for transplant as score inflation is reduced.

How will patients be notified?

Each program will need to communicate the changes to candidates who have an existing exception and explain the scoring to candidates as they submit new exceptions.

Median MELD at Transplant

What is Median MELD at Transplant (MMaT) and how will it be calculated?

If the proposal that is out for public comment is approved, MMaT will be calculated two different ways. During the transitional period between the implementation of the NLRB and the new liver distribution policy, all transplant programs within each DSA will have the same MMaT. This MMaT will be calculated 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 the DSA in the last 365 day cohort. The calculation does not include the scores for recipients who were status 1A or 1B at the time of transplant, or were transplanted with livers from living donors, DCD donors, or donors from hospitals outside of the transplant program's region.

Once the new liver distribution policy is implemented, MMaT will be calculated 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 listing hospital in the last 365 day cohort. This calculation does not include the scores for recipients who were status 1A or 1B at the time of transplant, or were transplanted with livers from living donors, DCD donors, or donors from donor hospitals more than 500 nautical miles away from the transplant hospital.

MMaT will be recalculated every 180 days based on the updated cohort.

How will I know what MMaT will be used for candidates at my program?

MMaT scores will be provided to transplant programs approximately two weeks prior to their use. In order to help programs prepare for conversations with their patients about how their exception scores might change, MMaT/DSA and MMaT/250 based on a recent cohort for each transplant program are posted [here](#). These scores will not necessarily be the exact MMaT scores that will be used when changes take place, but they are expected to be similar.

When will MMaT scores be updated?

Once the system transitions to MMaT/250, the MMaT for each transplant program will be updated every 180 days. Programs will be informed of their scores at least two weeks in advance of any updates.

Is the median transplant score for adults and children calculated differently?

Yes, MMaT only applies to candidates who are age 12 and older. Candidates who are under the age of 12 will be assigned a score based on the MPaT, which is calculated by using the median of the PELD scores at the time of transplant of recipients less than 12 years old across the nation.

For candidates age 12 and older who were registered on the waiting list before they turn 18, their exception scores will be awarded relative to MMaT, but are typically different from the scores awarded to adults with the same diagnosis. In most standard cases, adult candidates receive an exception score of 3 points less than MMaT, while a candidate who is at least 12, and registered before turning 18 would receive a score equal to MMaT. For the specific scores for a diagnosis, see to [OPTN/UNOS Policy 9.5 in the NLRB policy language](#) for standard exception scores and [NLRB guidance](#) for the scores recommended for the NLRB reviewers.

Is the MMaT stratified by blood group? Is there any difference in the MMaT in regards to ABO?

The MMaT is not calculated differently based on blood groups. After considering the data, the Liver Committee determined there to be minimal variation in MMaT between blood groups. This will continue to be monitored after implementation.

If my transplant program's MMaT or MPaT changes as a result of the 180 day update, will my patient's scores be affected?

If a program's MMaT or MPaT changes as a result of the 180 day update, the scores of candidates listed at the program will be changed in accordance with the updated scores. The new scores will be updated in the system at the same time for all affected exception candidates.

Participation

How can individuals from my organization participate in the NLRB?

Programs may have representatives participate on any or all of the specialty boards. They should email reviewboardstaff@unos.org for additional information.

Will representatives from the RRBs automatically transition to the NLRB?

No, review board members will not be automatically transitioned from the RRB to the NLRB. Each liver program may appoint a representative and an alternate to each of the Adult HCC and Adult Other Diagnoses boards. Each liver program that performs pediatric transplants may

appoint a representative and an alternate to the Pediatric board. These individuals can be the same as those currently serving on the RRB or someone else from the program.

Review Process

How do I complete an exception form for my candidates?

The process to complete an exception form has not changed. The exception forms are still accessed directly from the candidate record. The forms have a new look and have been designed to give you step-by-step instructions to complete the data for the candidate. Templates of the new forms have been posted on the Resources tab in UNetSM.

How long will it take to get a response to my exception score request?

Exception requests that go to the review board will be decided within 21 days. If the NLRB is unable to reach a decision within 21 days, the candidate will automatically receive the exception score.

What is the process that the NLRB will take to review exception score requests?

Exception score requests will be randomly assigned to a group of five reviewers on the relevant specialty board. The reviewers each see the exception request and vote electronically. In order for the request to be approved, four reviewers must agree on approving the request. If they are unable to reach a decision within 21 days, the candidate will automatically receive the requested score.

If the NLRB denies the exception request, the transplant program has 14 days to appeal the decision. If the program chooses to appeal, the request will be sent back to the same group of reviewers for consideration.

If the NLRB denies the appeal, the transplant program has 7 days to appeal that decision to the appeals review team (ART). The ART meets by conference call weekly to review appeals, and the transplant program may join the call to further explain why the requested exception score is appropriate for their patient. If the ART does not make a decision on the appeal within 14 days, the candidate will automatically receive the requested score.

If the ART denies an appeal, the transplant program has 7 days to appeal to the Liver Committee.

If an RRB denied my exception request, can I re-apply for the same exception to the NLRB?

Yes, a program can reapply for an exception that has been denied by the RRB.

Hepatocellular Carcinoma (HCC)

Will adult exception candidates with HCC still be required to wait for 6 months before the exception points are awarded, and will centers still need to submit extension forms every 3 months, even during the delay period?

There is still a delay in awarding exception points to adult HCC candidates, but the process is a little different. Under the new policy, HCC candidates will be awarded a score of MELD 6 for the initial application and the first extension. This is the lowest possible MELD score. The candidate's lab MELD score will be used on the match run during this period. If the candidate

continues to meet the criteria for the exception when the second extension is filed, the system will automatically assign a score equal to MMat minus three.

Additionally, MELD or PELD exception forms will now be valid for 90 days, rather than the 3-month time period. As a result, the scoring delay for adult HCC candidates will now be a total of 180 days, rather than 6 months. The waiting period begins on the date of the approval of the initial exception. The first extension form will be due 90 days after the approval of the initial exception, and the second extension will be due 90 days after that. If the candidate continues to meet the criteria for an HCC exception, they will receive the MMat minus three score at this point.

What exception score will HCC patients receive? Will there still be a MELD elevator?

The scoring system is outlined in *Table 9-9: HCC Exception Scores*, included below. Under the NLRB policy, adult HCC candidates who meet the requirements for a standard MELD exception will be assigned a score of 6 at the initial exception request and the first extension. After the first extension, they will be awarded a score of MMat minus three for every extension thereafter. There is no more MELD elevator.

HCC candidates who are at least 12 years old and were under the age of 18 at registration will be awarded a MELD score of 40 at the initial exception request and any extension thereafter.

HCC candidates who are less than 12 years old will be awarded a PELD score of 40 at the initial exception request and any extension thereafter. See Table 9-9 below for more details

Table 9-9: HCC Exception Scores

<u>Age</u>	<u>Age at registration</u>	<u>Exception Request</u>	<u>Score</u>
At least 18 years old	At least 18 years old	Initial and first extension	6
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

Will HCC exception scores still be capped at 34?

No, adult HCC exceptions and extensions will be awarded a score equal to MMat minus three as of the second extension. Pediatric HCC candidates will receive a MELD or PELD score of 40, starting with the initial exception form if they meet the standard HCC criteria.

What if a candidate has HCC, but their 3 month risk of mortality may warrant a MELD score greater than their laboratory MELD (during the first 6 months) or the HCC score of MMat minus three?

A center may petition the NLRB for an alternate MELD or PELD score if they feel that the assigned score does not reflect the candidate’s severity of illness. In order to make this request, a center may submit a new exception case to the NLRB using the HCC diagnosis and provide information to support the request. If the transplant program requests a score other than the policy assigned score, the application will be reviewed by the NLRB instead of being automatically approved.

If a patient has an HCC exception that requires submission to the NLRB, is it correct that those now must be submitted >21 days prior to the due date of the extension in order to allow enough time for the board to make a decision?

Programs can always submit an exception up to 30 days in advance of extension due date. If you have submitted the extension prior to extension due date, the candidate will remain at their exception score until the review board renders a decision regarding the extension.

Extensions

Will exception scores still increase with each extension?

No, there is no longer an increase in exception score assignment based on extension number. Programs can always request a higher score from the NLRB if they feel the policy assigned score is not appropriate for their candidate.

Is there an easy way for me to keep track of extension due dates for my exception patients?

The Waitlistsm report “MELD/PELD Exceptions – Extension Management” will assist you in the management of all candidates with approved MELD or PELD exceptions. The Liver Candidate MELD/PELD report will continue to be available, and remains a valuable tool in the management of all liver candidates based on their current medical urgency status.

Miscellaneous

What if a candidate meets the criteria for one of the nine standard diagnoses, but the standard policy assigned score doesn't accurately reflect the candidate's severity of illness?

A program may petition the NLRB for an alternate MELD or PELD score any time that an automatically assigned score does not reflect the candidate's severity of illness. The center will always have the option to submit a different score request to the NLRB for consideration. In order to make this request, a center may submit a new exception case to the NLRB using the same request form as the standard diagnosis and provide information to support the request for a different score.

Does hepatic artery thrombosis still receive a MELD of 40?

Yes, the committee preserved the MELD 40 score for this diagnosis.

Is there a cap for exception scores?

No, there is no cap for exception scores.

How will the NLRB affect candidates listed at multiple centers?

If an exception candidate, age 12 or older, is listed with the same medical criteria at multiple centers in different areas, it is possible they could have different scores at the different centers.

What will the review boards look for in narratives/justification for exceptions?

The board will be using guidance documents and clinical judgement to decide if the justification is adequate to grant the exception or the number of points requested. Transplant hospitals should reference the [guidance documents](#) and also provide clinically relevant information such as therapies that have been tried, donor offer summary, and additional hospitalizations.

Can images be submitted with appeals?

The current exception process does not allow any attachments to be submitted along with the required criteria. The justification narrative will be the only permissible additional submission.

Glossary of Abbreviations and Terms

Acuity Circles

Allocation

DSA Donor Service Area

MELD model or end stage liver disease (also known as Mayo end stage liver disease)

MMaT (also referred to as MM@T) median MELD at transplant

MPaT (also referred to as MP@T) median PELD at transplant

NLRB national liver review board

NM nautical miles

PELD pediatric end stage liver disease

RRB regional review board

Review board

Transition period