

## Improving Liver Allocation: General Implementation FAQ

This document provides background information and answers to frequently asked questions related to the implementation of the updated model for end stage liver disease (MELD) score, or MELD 3.0, and the updated pediatric end-stage liver disease score (PELD) score, or PELD creatinine (Cr), as well as other associated changes to liver allocation [policy slated for implementation in July 2023](#).

This document is intended to help transplant programs prepare for the upcoming implementation of the updated MELD and PELD scores and associated policy changes. It may also help answer questions from patients. Additional resources will be available on the OPTN website, including the following FAQ documents:

- [MELD 3.0: more detailed information about MELD 3.0](#)
- [Pediatric: more detailed information about PELD Cr, Status 1A, and Status 1B](#)
- [Patient-focused: information on the policy changes for patients](#)

If you have any additional questions, please contact [member.questions@unos.org](mailto:member.questions@unos.org) for assistance.

### Background

In June 2022, the OPTN Board of Directors approved a proposal from the OPTN Liver and Intestinal Organ Transplantation Committee that included changes to the current MELD and PELD scores, as well as the policy for Status 1A and Status 1B candidates. You can access more information about the proposal [here](#).

Separately, the OPTN Board of Directors approved updates to OPTN policy for hepatocellular carcinoma (HCC) MELD and PELD exceptions, also in June 2022. These changes will be implemented alongside the changes to the MELD and PELD scores and Status 1A and 1B criteria. You can read more about these changes [here](#).

In summary, the following will change upon implementation:

- **MELD 3.0:** This policy improves the accuracy of the MELD score by incorporating additional variables (albumin and sex), updating coefficients for existing variables, introducing interaction terms, and lowering the maximum creatinine value from 4.0 to 3.0 mg/dL.
- **PELD Cr:** This policy improves the accuracy of the PELD score by incorporating a creatinine variable to capture renal function, updating parameters for existing coefficients, and converting age and growth failure from categorical to continuous variables. PELD Cr also includes a factor for age-adjusted mortality, which aligns the risk of waitlist mortality at a given PELD Cr with the risk of mortality at the same MELD 3.0 score.
- **Status 1A:** This policy improves the Status 1A criteria for pediatric candidates with fulminant liver failure by updating the definition for hepatic encephalopathy. The new definition aligns with the definition developed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.
- **Status 1B:** This policy removes the MELD/PELD 25 threshold for liver-intestine and liver-alone candidates with chronic liver disease. The policy also changes the gastro-intestinal (GI) bleeding threshold for liver-alone candidates to match the definition of persistent mild shock or moderate shock, and it removes the Glasgow Coma Score (GCS) criteria for both liver-alone and

liver-intestine candidates. Finally, the policy updates sorting within Status 1B by prioritizing candidates with chronic liver disease, who are at the highest risk of waitlist mortality.

- **HCC Policy:** The updated policy language aligns with Liver Imaging Reporting and Data System (LI-RADS) terminology and classifications.<sup>1</sup> These changes will ensure the transplant community is using a consistent lexicon for HCC imaging but does not change which candidates will be approved for a MELD exception score.
- **Other changes:**
  - The policy updates how liver-intestine points are assigned to be based on candidate age at the time of registration, rather than current age.
  - The policy updates guidance for the pediatric National Liver Review Board (NLRB) to align with changes to PELD Cr and Status 1B criteria.

### **New Data Collection**

As part of these updates to liver allocation policy, there are also changes to data collection that transplant programs need to know.

For all MELD candidates (ages 12 and older), transplant programs will be required to submit an albumin value when editing a candidate record, as albumin is included in the MELD 3.0 calculation. Albumin is already required when adding an adult or adolescent liver candidate to the OPTN Waiting List.

For all PELD candidates (ages 11 and younger), transplant programs will be required to submit creatinine values in OPTN Waiting List when adding or editing a candidate record, as creatinine is included in the PELD Cr score. Creatinine is already required when adding or editing a candidate who is age 10 or older.

In addition, because MELD 3.0 includes additional points for adult female candidates, there are changes to data collection related to a candidate's sex outlined in more detail in the MELD 3.0 FAQ document.

### **Implementation Overview**

To give transplant programs time to submit the required data for their candidates, the implementation of MELD 3.0 and PELD Cr will occur in two phases.

#### Phase 1 :

- Planned to be implemented on June 15, 2023
- Will provide transplant programs time to enter required data prior to implementation of changes for MELD 3.0 and PELD Cr scores (Phase 2)
- Upon Phase 1 release:
  - The label on the current "Gender" field will be updated to "Birth sex" for all organs.
  - A new field, "Sex for Purposes of Adult MELD Calculation" will be deployed for all adult liver candidates (age 18 or older at the time of registration). This field will be required for all adult candidates registered after implementation of Phase 1. The field will be optional for adult candidates already on the OPTN Waiting List.

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<sup>1</sup> See CT/MRI LI-RADS v2018 Core available at <https://www.acr.org/>

## Phase 2:

- Planned to be implemented on July 13, 2023
- Upon Phase 2 release:
  - MELD 3.0 and PELD Cr scores will be calculated and used in allocation
  - Changes to criteria for pediatric Status 1A and Status 1B, updates to sorting within Status 1B, alignment of HCC policy language with LI-RADS terminology will go into effect
  - Albumin will become required for all MELD candidates
  - Creatinine will become required for all PELD candidates

## **Frequently Asked Questions**

### **Phase 1**

#### What do I need to do after Phase 1 is implemented?

During Phase 1, transplant programs are encouraged to review their candidates to ensure that all PELD candidates have updated creatinine values and all MELD candidates have updated albumin values. The OPTN will provide candidate-level reports in the Data Services Portal to help transplant programs identify candidates with missing data prior to implementation of Phase 2.

Also, after Phase 1 is implemented, transplant programs will be required to provide a response to the new data field, “Sex for Purposes of Adult MELD Calculation” for any adult candidate added to the OPTN Waiting List.

Transplant programs are also encouraged to provide a response to this new field for candidates already on the OPTN Waiting List if the candidate’s “Sex for Purposes of Adult MELD Calculation” is different than their birth sex. For more details see the MELD 3.0 FAQ document.

#### What exactly is changing with data collection related to a candidate’s sex?

The MELD 3.0 score includes 1.33 points for adult female candidates. These points are intended to address a disparity for female candidates in the liver allocation system. However, in order to ensure the points are provided appropriately, there are a few important changes to data collection related to a candidate’s sex.

First, across all organs, the field labeled “Gender” will now be labeled “Birth sex.” The new data label for this field does not change the purpose of the field, and you do not need to make any changes to your candidates’ information because of this update.

In addition, for adult liver candidates, there will be a new field deployed in Phase 1 called “Sex for Purposes of Adult MELD Calculation.” This field will account for situations where a candidate’s sex may be different than their birth sex.

See the MELD 3.0 FAQ document for more details.

#### What happens if I do not provide a required lab value for a candidate during Phase 1?

If you do not provide a required laboratory value used in MELD 3.0 or PELD Cr score before Phase 2 is implemented, the candidate’s calculated MELD or PELD score will be set to “null”

upon implementation of Phase 2 and their medical urgency status will be set to MELD or PELD 6. Users will see the reason why the MELD or PELD score is set to “null” in the OPTN Computer System.

Will I be able to see which candidates are missing lab values before implementation of Phase 2?

Yes, the OPTN Contractor will provide candidate-level reports in the OPTN Computer System that will include detailed information about the candidates at your transplant program. This report will be available approximately one week after Phase 1 is implemented. You can access the report within the OPTN Computer System by navigating to the Data Services Portal, then selecting OPTN Data Files on the left hand side of the screen, and then filtering the “Organ” field to “Liver”.

The report will include the following information for each candidate (in addition to general demographic information):

- Pediatric at time of listing (Yes/No)
- Birth Sex
- Sex for purposes of adult MELD calculation
- Liver-intestine candidate (Yes/No)
- Missing Lab Data

The report will also include the following information using **both the previous MELD and PELD scores and MELD 3.0 and PELD Cr**, based on the information that is available for the candidate:

- Calculated score
- Lab recertification due date
- Medical Urgency Status

These reports will help transplant programs see which candidates are missing required lab values, how candidate scores will likely change based on current information, and the adjusted lab recertification dates based on the new scores at the time of implementation. The reports will be updated weekly.

## Phase 2

What exactly is included in Phase 2 of implementation?

Phase 2 is the implementation of the policy changes, including:

- MELD 3.0
- PELD Cr
- Changes to criteria for pediatric Status 1A and Status 1B
- Changes to sorting within Status 1B
- Updates to HCC policy language to align with LIRADS
- Liver-intestine points based on age at registration
- Updates to PELD NLRB guidance

In addition, there will be further changes to data collection, including the following:

- Albumin will become required when editing a record for adolescent or adult liver transplant candidates.
- Creatinine will become required when adding a candidate or editing a record for all candidates age 11 and under.

For more detailed information about how MELD 3.0 and PELD Cr are calculated, please refer to the MELD and PELD Scores Calculator Guide, available on the OPTN Website.

## **General Questions about implementation**

### How will my candidate's scores change?

Upon implementation of MELD 3.0 and PELD Cr scores, candidates' scores will change. Some candidates' scores will increase, some will decrease, and some will remain the same. The new MELD and PELD calculations are better predictors of waitlist mortality and therefore, the new scores for each candidate will likely be a better representation of their true medical urgency for transplant. You can see what your candidates' new scores will be using the report available in the Data Services Portal described above.

### Will any candidate's scores decrease upon implementation?

Yes, some candidate's scores will decrease upon implementation. There is no specific group of candidates whose scores will decrease. However, the new scores are better predictors of waitlist mortality and urgency for transplant, and therefore any decrease is likely a reflection of that candidate's risk of waitlist mortality.

As always, if you believe your candidate's score is not an accurate reflection of their risk of waitlist mortality, you can submit a MELD or PELD exception request to the NLRB.

### How are adolescent candidates handled under the new score?

In the current liver allocation system, adolescent candidates (age at least 12 and less than 18) are assigned a MELD score. Under this new policy, adolescent candidates will continue to utilize MELD 3.0, but both male and female adolescent candidates will receive the 1.33 points that will be provided to all adult female candidates. This is based on data that shows there is no sex-based disparity in the adolescent population.

Both male and female adolescent candidates registered before turning 18 will maintain the 1.33 points if they remain on the OPTN Waiting List after turning 18.

### Am I required to send any information to my candidates?

The OPTN does not require you to provide any specific information to your candidates about the new policy. However, a patient-centered FAQ document is available on the OPTN Website, as well as other resources.

### How will my candidates' lab update schedule change upon implementation?

Upon implementation, each candidate's lab update schedule will be based on their new MELD or PELD score, reflecting the last time their labs were updated. The lab update schedule is outlined in [OPTN Policy 9.2: Status and Laboratory Values Update Schedule](#).

For example, if you have a candidate with a MELD score equal to 18 (before implementation) and you entered new lab values for the candidate on July 7, 2023, this candidate's next labs will be due in 90 days, on October 5, 2023.

If this candidate's MELD score increases to 19 upon implementation of MELD 3.0, his or her labs will become due in 30 days as outlined in OPTN Policy 9.2. In this example, the candidate's lab recertification date will change from October 5, 2023 (90 days from July 7, 2023) to August 6, 2023 (30 days from July 7, 2023).

### Will there be a grace period for labs due right after implementation?

Yes, there will be a grace period provided for candidates whose scores change upon implementation and their new lab recertification date is any of the following:

- Before the Phase 2 implementation date
- On the same day as the Phase 2 implementation date
- Less than 7 days after Phase 2 implementation.

For example, if you have an adult candidate with a MELD score equal to 24 (before implementation) and you entered lab values for the candidate on July 10, 2023, this candidate's next labs will be due in 30 days, or on August 9, 2023. However, let's say, this candidate's MELD 3.0 score increases to 25 at the time of implementation, which is on July 13. Candidates with a MELD score of 25 or greater are required to update their labs every 7 days. Therefore, at the time of implementation, this candidate's labs would become due on July 17 (7 days after July 10), which is only 4 days after implementation.

In cases like this, there will be a 7-day grace period from the date of implementation, meaning that you would have until July 20 to update this candidate's labs.

The 7-day grace period will apply to any candidates whose MELD or PELD score increases upon implementation such that their labs would otherwise be due prior to implementation, at the time of implementation, or within 7 days of implementation.

### How are liver-intestine points changing?

When a candidate is registered for a liver and an intestine, they are provided with additional MELD and PELD points to account for their increased mortality risk and need to access higher-quality donors. With this proposal, there is a small but important change to how these points are assigned based on the age of the candidate.

In [OPTN Policy 9.1.F: Liver-Intestine Candidates](#), adult liver-intestine transplant candidates automatically receive an additional increase in their MELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point

increase. Currently, these points are assigned based on the current age of the candidate. This means that a candidate will switch from the 23 points to the 10 percent increase on the day he or she turns 18 on the OPTN Waiting List.

After Phase 2 implementation, the points will be based on the candidate’s age at the time they are registered on the waitlist. As a result, if a liver-intestine candidate is registered before turning 18, they will continue to receive the 23 points for the duration of the time they remain on both the liver and intestine waitlist, even after turning 18. This change will be applied to candidates already on the OPTN Waiting List at the time of implementation.

**Liver Imaging Reporting and Data System (LI-RADS):**

Separate from the proposal to update MELD, PELD, Status 1A, and Status 1B, the OPTN Board of Directors also approved a [proposal](#) in June 2022 to update the policy language for hepatocellular carcinoma (HCC) exceptions to align with Liver Imaging Reporting and Data System (LI-RADS) terminology. These changes will be implemented at the same time as the Phase 2 implementation of the MELD and PELD scores.

What is changing with HCC policy?

The terminology used in OPTN policy for HCC exceptions is changing to align with terminology used by radiologists as documented in the LI-RADS v2018 manual. These changes are summarized in the table below:

**Table 1: HCC Policy Changes**

Previous Policy Language	New Policy Language
Local regional	Locoregional
Lesions	Class 5 lesions
T2 lesions	T2 Stage
Residual lesions	Viable Lesions
CT or MRI	Dynamic-contrast enhanced CT or MRI
Scan is inadequate or incomplete	Lesion cannot be categorized due to image degradation or omission
OPTN Class 0	NC – Not Categorizable
Increase contrast enhancement, relative to hepatic parenchyma, on late arterial phase	Nonrim arterial phase hyper-enhancement
Washout during the later contrast phases and peripheral rim enhancement on delayed phase	Nonperipheral washout
Maximum diameter increase of 50% documented on serial MRI or CT obtained 180 days or less apart	Threshold growth defined as size increase of a mass by $\geq 50\%$ in $\leq 180$ days on MRI or CT
Washout on portal venous/delayed phase	Nonperipheral washout
Peripheral rim enhancement	Enhancing capsule
Ablated	Treated by locoregional therapy

Will any candidates lose their HCC exception?

No candidates will lose their HCC exceptions as a result of these policy changes.

Are the criteria for HCC exceptions changing?

No, the actual criteria for an HCC exception are not changing. The terminology will change, as outlined above, but the substance of the policy and guidance is not changing.