

Can you summarize how HCC exceptions changed with the December 12, 2017 implementation?

- Candidates with lesions meeting T2 criteria but with a most recent alpha-fetoprotein (AFP) level greater than 1000 ng/mL will not be eligible for an automatically approved standardized MELD exception and their application will require review by the Regional Review Board (RRB).
- The system will enforce the requirement that candidates have a chest CT to rule out metastatic disease in order for the form to be auto-approved.
- Centers must also report the AFP coinciding with the time that the original tumor imaging was obtained. Candidates with AFP levels greater than 1000 ng/mL will be eligible for an automatically approved standardized MELD exception if the AFP level falls below 500 ng/mL after local-regional therapy. If the AFP level returns to a level greater than or equal to 500 ng/mL at any time following local-regional therapy, the application will require review by the RRB.
- New criteria establish eligibility for certain candidates whose lesions can be downstaged. Candidates with Original/Presenting lesions that exceed T2 criteria, but are within downstaging criteria will be eligible for automatic approval if their residual lesions fall within T2 criteria after local-regional therapy.
- Adult HCC candidates will follow a new schedule of automatic score assignment, that increases the scores on the 3rd, 4th and 5th extension compared to the previous schedule.

ADULT	Current	Revised
initial form	Calculated MELD	Calculated MELD
1st extension	Calculated MELD	Calculated MELD
2nd extension	28	28
3rd extension	29	30
4th extension	31	32
5th extension	33	34
6th extension	34	34

- All pediatric candidates' (less than age 18 at time of registration) HCC applications will require review by the RRB. Pediatric HCC candidates will receive a MELD/PELD score of 40. Please note, there will no longer be a cap of 34 or 6-month delay prior to assigning the exception score for pediatric candidates.

Why is the score for pediatric HCC candidates different from the HCC policy notice?

This score assignment of 40 is a change from the original HCC policy approved by the OPTN/UNOS Board in December 2016, but reflects the assignment these candidates will receive under the National Liver Review Board (NLRB). The NLRB proposal language was approved by the OPTN/UNOS Board in June 2017 and will be fully implemented later in 2018 (see [Policy Notice](#)). The exception score for pediatric

candidates is being implemented at this time to prevent unnecessary disruption in score assignments between the HCC and NLRB releases.

Were changes made to the standard HCC exception form for candidates with a single treated lesion between 2 and 3 cm?

Although at the time of public comment for this proposal the Liver Committee initially considered eliminating priority for HCC candidates with single well-treated lesions, after reviewing public comment the Committee determined that the single small lesion criteria should be removed. The single small lesion criteria are **not** included in the policy changes implemented on December 12, 2017, nor are they in the policy update implemented on February 5, 2018.

Why are candidates that meet T2 criteria, but with an AFP greater than 1000 ng/mL, not initially eligible for an automatically approved standardized exception?

There is increasing evidence that clinical factors beyond lesion size and number of lesions are associated with a greater risk of HCC recurrence and poor post-transplant outcomes. The Committee identified an AFP of 1000 ng/mL as a threshold that indicates a high risk of HCC recurrence and therefore not qualified for an increased MELD score unless the AFP is reduced and remains within acceptable levels suggestive of a lower risk of recurrence.

How does the new policy regarding downstaging work?

Candidates initially presenting with lesions that meet the downstaging criteria will be eligible for an automatically approved HCC exception if they complete local-regional treatment and their residual lesions subsequently fall within T2 criteria. After downstaging to T2, the center can submit a standard HCC exception form for these candidates. Adult candidates will then be subject to the same 6 month delay as candidates that initially present within T2.

What will happen to existing HCC candidates at time of implementation?

Pediatric candidates with approved HCC forms on the day of implementation will be updated to a revised MELD or PELD score of 40. Adult candidates with auto approved extensions will be evaluated to determine if the form meets the new policy eligibility criteria. If a form does meet the new criteria, the auto-approval remains in effect, and the candidate may receive an increase in their score as reflected by the new score schedule (see table above). If a form does not meet the new criteria, the candidate's score will remain in effect until the form is due for extension. After implementation, all candidates must meet the new policy criteria for auto approval when applying for an extension.

Has anything changed with extensions of HCC exceptions?

Yes. On extension, adult HCC forms will no longer be auto approved if either:

- The candidate has an AFP greater than 1000 ng/mL, or
- The candidate's initial AFP was reported as greater than 1000 ng/mL, but the candidate currently has an AFP greater than or equal to 500 ng/mL.

If these criteria are not met, the extension application will require review by the RRB. Extension forms for pediatric HCC candidates must be submitted to the RRB for approval. Pediatric HCC extension forms will be assigned a MELD or PELD score of 40.

Will the current cap and delay for MELD and PELD scores still apply?

For adult candidates, the answer is yes. Adult HCC candidates must wait at their calculated MELD score for six months before receiving exception points, and the maximum MELD score for adult HCC candidates is capped at 34. Pediatric candidates do not have to wait at their calculated MELD or PELD score for 6 months before receiving exception points, and will receive a score of 40 MELD or PELD points if the exception request is approved by the RRB.

Will programs still need to submit extension forms for adult candidates every 3 months during the first 6 months when they will not receive priority MELD points?

Yes. The 6 month period begins from the date of the approval of the initial exception, and the first extension form will still be due at 3 months. The candidate's calculated lab MELD score will be used on the match run during this period. The third application would be approved for a MELD of 28. Please note, the delay does not apply to pediatric candidates.

Is there an easy way for me to keep track of extension due dates during the 6 months delay period?

You can use the Waitlistsm report "MELD/PELD Exceptions – Extension Management" to assist you in the management of all candidates with approved MELD/PELD exceptions. The Waitlistsm report "Liver Candidate MELD/PELD Report" is also a valuable tool in the management of all liver candidates based on their current medical urgency status.

What if an adult 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 than the HCC score cap of 34?

A center may petition the RRB for an alternate MELD 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 must submit a new exception case to the RRB using the "other specify" diagnosis and providing documentation to support the request.