

OPTN/UNOS Policy Notice

Revisions to National Liver Review Board Policies

Sponsoring Committee:	Liver and Intestinal Organ Transplantation Committee
Policy/Bylaws Affected:	Policy 1.2 (Definitions); 1.3 (Variances); 1.4.E (OPTN Computer Match Outages); 5.4.B (Order of Allocation); 5.10.C (Other Multi-Organ Combinations); 9.1.A (Adult Status 1A Requirements); 9.1.C (Pediatric Status 1B Requirements); 9.1.D (MELD Score); 9.1.F (Liver-Intestine Candidates); 9.2 (Status and Laboratory Values Update Schedule); 9.3 (Status Exceptions), 9.4 (MELD or PELD Score Exceptions); 9.5 (Specific Standardized MELD or PELD Score Exceptions); 9.10.A (Registration Accuracy); 9.10.B (Review of Status 1A and 1B Candidate Registrations); (Bylaws 9.3 (Review Boards), and Appendix M (Definitions)
Public Comment:	January 23, 2017 – March 24, 2017 October 8, 2018 – November 1, 2018
Effective Date:	January 31, 2019

Problem Statement

At the June 2017 Board of Directors' Meeting, the Board adopted policy changes outlined in *Proposal to Establish a National Liver Review Board* (hereafter "2017 proposal") that established the National Liver Review Board (NLRB). In December of 2018, before the 2017 proposal was implemented, the Board adopted *Eliminate the Use of DSAs and Regions in Liver Distribution* (hereafter "2018 proposal") which included additional changes affecting the NLRB. As such, the NLRB policy set for implementation combines portions of both of these proposals. This Policy Notice addresses the policy changes adopted in the 2018 proposal and those that were adopted in the 2017 proposal that were not changed by the 2018 proposal.

Summary of Changes

The new Policies and Bylaws accomplish the following:

- Establish a National Liver Review Board (NLRB) to provide fair, equitable, and prompt peer review of exceptional candidates. The NLRB will be comprised of three specialty boards including Adult HCC, Adult Other Diagnosis, and Pediatrics.
- Eliminate the regional agreements; NLRB members will use the complementary NLRB guidance documents to assess the most common types of exceptions.
- Make the award of exception points for standardized exception requests more uniform and efficient by creating a formula tying the exception points to the median MELD at transplant.

- Reduce the workload for reviewers and eliminate unnecessary delays by automating all standardized MELD or PELD exceptions in Policy.

The changes to NLRB take effect before the distribution changes adopted in the 2018 liver proposal, which allows time between implementation dates for all existing exceptions to be reviewed under the new system. This will allow for correction of inequities and inefficiencies in exception scoring in the current regional review board system.

The full changes included in the 2017 and 2018 proposals are available on the OPTN website under the “Governance: Policy Notices” tab. See <https://optn.transplant.hrsa.gov/governance/policy-notice/>.

What Members Need to Do

Liver programs will need to prepare to implement these new Policies. Similar to the current review board system, every active liver transplant program may appoint a representative and alternate to each of the adult specialty boards. A liver transplant program with an active pediatric component may appoint a representative and an alternate to the pediatric specialty board. Transplant programs are encouraged to appoint representatives from both hepatology and surgery who have active transplant experience. Liver transplant programs are not required to provide a representative to the NLRB.

Representative and alternate responsibilities are detailed in the *National Liver Review Board Operational Guidelines*, are available as part of the implementation of this proposal. Members can find detailed information about representative and alternate responsibilities in the National Liver Review Board Operational Guidelines. These Guidelines are on the OPTN website: Resources > Liver & Intestine. To enable the automatic approval of the standardized exceptions, members will have to submit required information in discrete data fields in UNet instead of the narrative form currently used.

Members also need to be aware of and educate their staff on the new scoring for standardized exceptions requests.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (example).

1.2 Definitions

Allocation MELD or PELD Score

The highest exception or calculated MELD or PELD score available to the candidate according to Policy. Allocation MELD or PELD Score includes liver-intestine points.

Calculated MELD or PELD Score

The highest non-exception MELD or PELD score available to the candidate according to Policy. Calculated MELD or PELD score excludes liver-intestine points.

Geographical Area

A physical area used to group potential transplant recipients in a classification. ~~OPTN Policy uses the following geographical areas for organ allocation: DSA, region, nation, and zones.~~

Match MELD or PELD Score

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

Region

For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the Region in which they are located. The Regions are as follows:

- Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont
- Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO.
- Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico
- Region 4: Oklahoma and Texas
- Region 5: Arizona, California, Nevada, New Mexico, and Utah
- Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington
- Region 7: Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin
- Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming
- Region 9: New York and Western Vermont
- Region 10: Indiana, Michigan, and Ohio
- Region 11: Kentucky, North Carolina, South Carolina, Tennessee, and Virginia

1.3 Variances

1.3.A Acceptable Variances

Permissible variances include, but are not limited to:

- Alternative allocation systems
- Alternative local units
- Sharing arrangements
- Alternative point assignment systems

The following principles apply to *all* variances:

1. Variances must comply with the NOTA and the Final Rule.
2. Members participating in a variance must follow all rules and requirements of the OPTN Policies and Bylaws.
3. If the Board later amends an OPTN Policy to contradict with a variance, the Policy amendment will not affect the existing variance.
- ~~4. There must be a single waiting list for each organ within each DSA.~~
- ~~5. Where the alternative local unit created by a variance is a subdivision of the OPO's DSA, the OPO will allocate organs to the remainder of the DSA after allocating organs to this alternative local unit.~~
- ~~6.~~ 4. If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support.
- ~~7.~~ 5. The Board of Directors may extend, amend, or terminate a variance at any time.

1.4.E OPTN Computer Match Program Outages

If the OPTN Contractor and members cannot communicate by any method and the OPTN computer match program is either not accessible or not operational, affected OPOs:

1. Must refer to recent matches of similar blood type and body size for ranking local transplant candidates.
2. Must use local transplant program waiting lists to match the best organ with waiting transplant candidates.

3. Must document and report to the OPTN Contractor their process for allocation during the outage.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN Contractor. The host OPO must re-execute the match run to allocate the organ.
- ~~5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate the organ according to Policy.~~
6. Extra vessels allocated with an organ but not required for its transplant can be shared according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
- ~~6.~~ 7. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

5.10.C Other Multi-Organ Combinations

When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to Table 5-4 below; ~~if the donor's DSA is the same DSA where the multi-organ candidate is registered.~~

Table 5-4: Allocation of Multi-Organ Combinations

<u>Organ</u>	<u>Candidate is registered within the following geographical area:</u>
<u>Heart</u>	<u>Same DSA as the donor hospital</u>
<u>Liver</u>	<u>150 nautical miles from the donor hospital</u>
<u>Lung</u>	<u>250 nautical miles from the donor hospital</u>

If the multi-organ candidate is on a waiting list outside the ~~donor's DSA~~ geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.

Policy 9: Allocation of Livers and Liver-Intestines

9.1 Status and Score Assignments

Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status.

Liver candidates at least 18 years old at the time of registration may be assigned *any* of the following:

Adult status 1A
Calculated MELD score
Exception MELD score
Inactive status

Liver candidates less than 18 years old at the time of registration may be assigned *any* of the following:

Pediatric status 1A
Pediatric status 1B
Calculated MELD or PELD score
Exception MELD or PELD score
Inactive status

Liver candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, will be classified as a 12 to 17 year old for the purposes of allocation in:

- *Policy 9.8.F: Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old*
- *Policy 9.8.G: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old*
- *Policy 9.8.K: Allocation of Liver-Intestines from Non-DCD Donors Less than 11 Years Old*

If the candidate is removed from the waiting list at any time and returns to the waiting list after turning 18 years old, the candidate must then be registered as an adult.

9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not registered as status 1A until this form is submitted. When reporting laboratory values to the OPTN Contractor, transplant hospitals must submit the most recent results including the dates of the laboratory tests.

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:
 - a. Fulminant liver failure, without pre-existing liver disease and currently in the intensive care unit (ICU), defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease, and has at least *one* of the following criteria:
 - i. Is ventilator dependent
 - ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iii. Has an international normalized ratio (INR) greater than 2.0
 - b. Anhepatic
 - c. Primary non-function of a transplanted whole liver within 7 days of transplant, with aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
 - International normalized ratio (INR) greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L

All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

- d. Primary non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
 - INR greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L
- e. Hepatic artery thrombosis (HAT) within 7-days of transplant, with AST greater than or equal to 3,000 U/L and at least *one* of the following:
 - INR greater than or equal to 2.5
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L

All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

~~Candidates with HAT in a transplanted liver within 14 days of transplant not meeting the above criteria will be listed with a MELD of 40.~~

- f. Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
2. The candidate has at least *one* of the following conditions:
 - a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within 56 days of the first signs and symptoms of liver disease and has at least *one* of the following criteria:
 - i. Is ventilator dependent
 - ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iii. Has an international normalized ratio (INR) greater than 2.0
 - b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
 - i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
 - ii. INR greater than or equal to 2.5
 - iii. Total bilirubin greater than or equal to 10 mg/dL
 - iv. Acidosis, defined as *one* of the following:
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25

- Lactate greater than or equal to 4 mmol/L

All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

- c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant
- d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
2. The candidate has *one* of the following conditions:
 - a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.
 - b. The candidate has an organic acidemia or urea cycle defect and an approved MELD or PELD exception meeting standard criteria score for metabolic disease score of 30 points for at least 30 days.
 - c. Chronic liver disease with a calculated MELD ~~greater than 25 for adolescent candidates 12 to 17 years old, or a calculated PELD greater than 25 for candidates less than 12 years old,~~ and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.
 - d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

9.1.D MELD Score

Candidates who are at least 12 years old receive an initial MELD_(i) score equal to: $0.957 \times \text{Loge}(\text{creatinine mg/dL}) + 0.378 \times \text{Loge}(\text{bilirubin mg/dL}) + 1.120 \times \text{Loge}(\text{INR}) + 0.643$

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 4.0 mg/dL:

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior 7 days
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior 7 days

The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

For candidates with an initial MELD score greater than 11, the MELD score is then re-calculated as follows:

$$\text{MELD} = \text{MELD}_{(i)} + 1.32 \times (137 - \text{Na}) - [0.033 \times \text{MELD}_{(i)} \times (137 - \text{Na})]$$

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

~~If a candidate's recalculated MELD score requires recertification within 7 days of implementation based on *Table 9-1: Liver Status Update Schedule*, the transplant hospital will have 7 days to update laboratory values. If after 7 days the laboratory values are not updated, the candidate will be re-assigned to the previous lower MELD score~~

9.1.E PELD Score

Candidates who are less than 12 years old receive a PELD score equal to:

$$0.436 (\text{Age} (<1 \text{ YR.})) - 0.687 \times \text{Loge}(\text{albumin g/dL}) + 0.480 \times \text{Loge}(\text{total bilirubin mg/dL}) + 1.857 \times \text{Loge}(\text{INR}) + 0.667 (\text{Growth failure} (<- 2 \text{ Std. Deviations present}))$$

The PELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

Scores for candidates registered for liver transplantation before the candidate's first birthday continue to include the value of 0.436 until the candidate is 24 months old.

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.

A candidate has growth failure if the candidate is more than two standard deviations below the candidate's expected growth based on age and gender using the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.

9.1.F Liver-Intestine Candidates

~~Adult liver c~~ Candidates awaiting a liver-intestine transplant who are also registered and active on both waiting lists ~~the waiting list for an intestine transplant at that transplant hospital will~~ automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old will

receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that the transplant was completed.

9.2 Status and Laboratory Values Update Schedule

The OPTN Contractor will notify the transplant hospital within 2 days ~~48 hours~~ of the deadline for recertification when a candidate's laboratory values need to be updated. Transplant hospitals must recertify a candidate's values according to *Table 9-1*. ~~These data must be based on the most recent clinical information, laboratory tests, and diagnosis and include the dates of all laboratory tests.~~

When reporting laboratory values to the OPTN Contractor, transplant hospitals must submit the most recent results including the dates of the laboratory tests. In order to change a MELD or PELD score voluntarily, all laboratory values must be obtained within the same 2 day ~~48-hour~~ period.

Table 9-1: Liver Status Update Schedule

If the candidate is:	The new laboratory values must be reported every:	And when reported, the new laboratory values must be no older than :
Status 1A or 1B	7 days	48 hours <u>2 days</u>
MELD 25 or greater (ages 18 or older)	7 days	48 hours <u>2 days</u>
MELD/PELD 25 or greater (less than 18 years old)	14 days	72 hours <u>3 days</u>
MELD/PELD 19 to 24	1 Month <u>30 days</u>	7 days
MELD/PELD 11 to 18	3 months <u>90 days</u>	14 days
MELD/PELD 10 or less	12 months <u>365 days</u>	30 days

Status 1B candidates have these further requirements for certification:

- Candidates with a gastrointestinal bleed as the reason for the initial status 1B upgrade criteria must have had another bleed in the past 7 days immediately before the upgrade in order to recertify as status 1B.
- Candidates indicating a metabolic disease or a hepatoblastoma require recertification every 90 days ~~three months~~ with lab values no older than 14 days.

If a candidate is not recertified by the deadline according to *Table 9-1*, the candidate will be re-assigned to their previous lower MELD or PELD score. The candidate may remain at that previous lower score for the period allowed based on the recertification schedule for the previous lower score, minus the time spent in the uncertified score.

If the candidate remains uncertified past the recertification due date for the previous lower score, the candidate will be assigned a MELD or PELD score of 6. If a candidate has no previous lower MELD or PELD score, and is not recertified according to the schedule, the candidate will be reassigned to a MELD or PELD score of 6, or will remain at the uncertified PELD score if it is less than 6.

9.2.A Recertification of Status 1A or 1B

Transplant hospitals must submit a completed *Liver Status 1A or 1B Justification Form* to the OPTN Contractor for *each* recertification as a status 1A or 1B. A request to continue as status 1A

or 1B beyond 14 days accumulated time will result in a review of all status 1A or 1B liver candidate registrations ~~within the donation service area (DSA)~~ at the transplant hospital. A review will not occur if the request was for a candidate meeting the requirements for hepatoblastoma in *Policy 9.1.C: Pediatric Status 1B Requirements* or a metabolic disease in *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*.

9.3 ~~Score and Status Exceptions~~

~~If a candidate's transplant program believes that a candidate's MELD or PELD score does not appropriately reflect the candidate's medical urgency, the transplant physician may apply to the Regional Review Board (RRB) for a MELD or PELD score exception.~~

~~The Liver and Intestinal Organ Transplantation Committee establishes guidelines for review of status and MELD/PELD score exception requests.~~

If a candidate's transplant program believes that a candidate's current status does not appropriately reflect the candidate's medical urgency for transplant, the transplant physician program may register a candidate at the an exceptional status. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review all exception candidates registered as status 1A or 1B according to the criteria in Policy 9.3: Score and Status Exceptions, and The Liver and Intestinal Organ Transplantation Committee may refer these cases to the Membership and Professional Standards Committee (MPSC) for review according to *Appendix L* of the OPTN Bylaws.

~~9.3.D Pediatric Liver Candidates with Metabolic Diseases~~

~~A pediatric liver transplant candidate with a urea cycle disorder or organic acidemia will receive a MELD/PELD score of 30. If the candidate does not receive a transplant within 30 days of being registered with a MELD/PELD of 30, then the candidate's transplant physician may register the candidate as a status 1B.~~

~~If a candidate has a different metabolic disease and the candidate's transplant program believes that a candidate's MELD/PELD score does not appropriately reflect the candidate's medical urgency, then the transplant physician may request an exception according to *Policy 9.3: Score Exception Requests*. However, the RRB will review these applications based on standards jointly developed by the Liver and Intestinal Organ Transplantation Committee and the Pediatric Transplantation Committee.~~

~~9.3.E Candidates with Cholangiocarcinoma~~

~~A candidate will receive the MELD/PELD exception in *Table 9-2: Specific MELD/PELD Exceptions* for cholangiocarcinoma, if the candidate's transplant hospital meets all the following qualifications:~~

- ~~1. Submit a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include all of the following:~~
 - ~~a. Candidate selection criteria~~
 - ~~b. Administration of neoadjuvant therapy before transplantation~~
 - ~~c. Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease~~
 - ~~d. Any data requested by the Liver and Intestinal Organ Transplantation Committee~~
- ~~2. Document that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and one of the following:~~
 - ~~a. Biopsy or cytology results demonstrating malignancy~~
 - ~~b. Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis~~
 - ~~c. Aneuploidy~~

- The tumor must be considered un-resectable because of technical considerations or underlying liver disease.
3. If cross-sectional imaging studies demonstrate a mass, the mass must be less than three cm.
 4. Intrahepatic and extrahepatic metastases must be excluded by cross-sectional imaging studies of the chest and abdomen at the time of the initial application for the MELD/PELD exception and every three months before the MELD/PELD score increases.
 5. Regional hepatic lymph node involvement and peritoneal metastases must be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
 6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) must be avoided because of the high risk of tumor seeding associated with these procedures.

9.4 MELD or PELD Score Exceptions

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

9.4.A MELD/ or PELD Score Exception Applications Requests

An MELD or PELD score exception application request must include all of the following:

1. Include a request for a specific MELD or PELD score.
2. Justify why accepted A justification of how the medical criteria supports that the candidate has a higher MELD or PELD score and explain
3. An explanation of how the patient's candidate's current condition and potential for benefit from transplant would be comparable to that of other candidates with that MELD or PELD score.

Approved MELD or PELD exception scores are valid for 90 days from the date the exception is approved.

9.4.B Review of Exceptions by the RRB and Committees NLRB and Committee Review of MELD or PELD Exceptions

Each RRB must review requests within 21 days of the date the application is submitted to the OPTN Contractor. If the RRB does not approve the application within 21 days, then the candidate's transplant physician may either:

- Appeal the decision.
- Register the candidate at the requested MELD or PELD score following a conference call with the RRB. However, these cases will be automatically referred to the Liver and Intestinal Organ Transplantation Committee. The Liver and Intestinal Organ Transplantation Committee may refer these cases to the MPSC for appropriate action according to Appendix L of the OPTN Bylaws.

The RRB will report its decisions and justifications to the Liver and Intestinal Organ Transplantation Committee and the MPSC. The Committees determine whether the MELD or PELD score exceptions are consistently evaluated and applied within OPTN regions and across the country. Additionally, the Committees evaluate whether existing MELD or PELD score criteria continue to be appropriate.

The NLRB must review exception or extension requests within 21 days of the date the request is submitted to the OPTN Contractor. If the NLRB fails to make a decision on the initial exception or

extension request by the end of the 21 day review period, the candidate will be assigned the requested MELD or PELD exception score.

9.4.B.i: NLRB Appeals

If the NLRB denies an exception or extension request, the candidate's transplant program may appeal to the NLRB within 14 days of receiving the denial.

The NLRB must review appeals within 21 days of the date the appeal is submitted to the OPTN Contractor. If the NLRB fails to make a decision on the appeal by the end of the 21 day appeal period, the candidate will be assigned the requested MELD or PELD exception score.

9.4.B.ii: Appeals Review Team (ART) Conference

If the NLRB denies the appeal for an exception or extension request, the candidate's transplant program may further appeal to the Appeals Review Team (ART) within 7 days of receiving notification of the denial. If the transplant program appeals the exception or extension request to the ART, the ART must review the request within 14 days of the date the appeal is submitted to the OPTN Contractor. If the ART fails to make a decision on the appealed request by the end of the 14 day ART appeal review period, the candidate will be assigned the requested MELD or PELD exception score.

9.4.B.iii Committee Appeals

If the ART denies the appeal for an exception or extension request, the candidate's transplant program may appeal to the Liver and Intestinal Organ Transplantation Committee within 7 days of receiving notification of the denial.

9.4.C MELD or PELD Score-Exception Extensions

~~Transplant hospitals may apply for a MELD or PELD score exception extension to receive the equivalent of a 10 percentage point increase in candidate mortality every 3 months as long as the candidate continues to meet the exception criteria. Extensions must be prospectively reviewed by the RRB.~~

A candidate's approved exception score will be maintained if the transplant hospital enters a MELD or PELD Exception Score Extension Request the extension application more than 3 days before the due date according to *Table 9-1: Liver Status Update Schedule*, even if the RRB NLRB does not act before the due date. If the extension application request is later denied or if no MELD or PELD Exception Score Extension Request is submitted before the due date, then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

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

9.4.D Calculation of Median MELD or PELD at Transplant¹

Median MELD at transplant (MMaT) 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 the DSA of the candidate's transplant hospital in the last 365 days.

Median PELD at transplant (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 MMaT and MPaT calculations exclude recipients who are either of the following:

1. Transplanted with livers from living donors, DCD donors, and donors from donor hospitals outside the region of the transplant hospital
2. Status 1A or 1B at the time of transplant.

The OPTN Contractor will recalculate the MMaT and MPaT every 180 days using the previous 365-day cohort. If there have been fewer than 10 qualifying transplants within the DSA of the candidate's transplant hospital in the previous 365 days, the MMaT will be calculated based on the previous 730 days.

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

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

9.5 Specific Standardized MELD or PELD Score Exceptions

~~Candidates meeting the criteria in *Table 9-2: Specific Standardized MELD/PELD Exceptions* are eligible for MELD or PELD score exceptions that do not require evaluation by the full RRB. The transplant program must submit a request for a specific MELD or PELD score exception with a written narrative that supports the requested score. Additionally, a candidate may receive a higher MELD or PELD score if the RRB has an existing agreement for the diagnosis. These agreements must be renewed on an annual basis.~~

¹ Portions of this section will be changed with the implementation of *Liver and Intestine Distribution Using Distance from Donor Hospital*, adopted by the OPTN/UNOS Board of Directors at its December 2018 meeting.

Table 9-2: Specific Standardized MELD/PELD Exceptions

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cholangiocarcinoma	The information required according to <i>Policy 9.3.E: Candidates with Cholangiocarcinoma.</i>	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Cystic Fibrosis	The candidate has signs of reduced pulmonary function with forced expiratory volume at one second (FEV ₁) that falls below 40 percent.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Familial Amyloid Polyneuropathy (FAP)	<i>All of the following:</i> <ol style="list-style-type: none"> 1. Clear diagnosis of FAP. 2. Echocardiogram showing the candidate has an ejection fraction greater than 40 percent. 3. Ambulatory status. 4. Identification of transthyretin (TTR gene) mutation (Val30Met vs. non-Val30Met). 5. Biopsy-proven amyloid in the involved organ. 	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in <i>Policy 9.1.A: Adult Status 1A Requirements</i>	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	The information required according to <i>Policy 9.3.F: Candidates with Hepatocellular Carcinoma (HCC).</i>	<i>See Policy 9.3.F: Candidates with Hepatocellular Carcinoma (HCC).</i>
Hepatopulmonary Syndrome (HPS)	<i>All of the following:</i> <ol style="list-style-type: none"> 1. Clinical evidence of portal hypertension. 2. Evidence of a shunt. 3. PaO₂ less than 60 mmHg on room air. 4. No significant clinical evidence of underlying primary pulmonary disease. 	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months that the candidate's PaO ₂ remains under 60 mmHg.
Metabolic Disease	The information required according to <i>Policy 9.3.D: Pediatric Liver Candidates with Metabolic Diseases.</i>	<i>See Policy 9.3.D: Pediatric Liver Candidates with Metabolic Diseases.</i>

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Portopulmonary Hypertension	<p>The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention.</p> <p>The diagnosis must also include <i>all</i> of the following:</p> <ol style="list-style-type: none"> 1. Initial mean pulmonary arterial pressure (MPAP) level. 2. Initial pulmonary vascular resistance (PVR) level. 3. Initial transpulmonary gradient to correct for volume overload. 4. Documentation of treatment. 5. Post-treatment MPAP less than 35 mmHg. 6. Post treatment PVR less than 400 dynes/sec/cm⁻⁶. 	<p>Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months if a repeat heart catheterization confirms that the mean pulmonary arterial pressure (MPAP) remains below 35 mmHg.</p>
Primary Hyperoxaluria	<p>The candidate has <i>all</i> of the following:</p> <ol style="list-style-type: none"> 1. Is registered for a combined liver-kidney transplant. 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis. 3. Glomerular filtration rate (GFR) less than or equal to 25 mL/min, by six variable Modification of Diet in Renal Disease formula (MDRD6) or direct measurement of iothalamate or iohexol, for 42 or more days. 	<p>Will receive a MELD score of 28 or PELD score of 41; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.</p>

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

- Cholangiocarcinoma (CCA), according to *Policy 9.5.A: Requirements for Cholangiocarcinoma MELD or PELD Score Exceptions*
- Cystic fibrosis, according to *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions*
- Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions*
- Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions*
- Metabolic disease, according to *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*
- Portopulmonary hypertension, according to *Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions*

- Primary hyperoxaluria, according to *Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions*
- Hepatocellular carcinoma, according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception*

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

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

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

1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include *all* of the following:
 - Candidate selection criteria
 - Administration of neoadjuvant therapy before transplantation
 - Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
 - Any data requested by the Liver and Intestinal Organ Transplantation Committee
2. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and at least one of the following:
 - Biopsy or cytology results demonstrating malignancy
 - Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
 - Aneuploidy

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

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

Table 9-2: CCA Exception Scores

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

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

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

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

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

Table 9-3: Cystic Fibrosis Exception Scores

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

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

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

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

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

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

Table 9-4: FAP Exception Scores

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

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

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

9.5.D Requirements for Hepatic Artery Thrombosis (HAT) MELD-Score Exceptions

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

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

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

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

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

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

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

Table 9-5: HPS Exception Scores

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

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

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 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 a score according to *Table 9-6* below.

Table 9-6: Metabolic Disease Exception Scores

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

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

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

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

1. Initial mean pulmonary arterial pressure (MPAP) level
2. Initial pulmonary vascular resistance (PVR) level
3. Initial transpulmonary gradient to correct for volume overload
4. Documentation of treatment
5. Post-treatment MPAP less than 35 mmHg within 90 days prior to submission of the initial exception
6. Post treatment PVR less than 400 dynes*sec/cm⁵ or less than 5.1 Wood units (WU), on the same test date as post-treatment MPAP less than 35 mmHg

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

Table 9-7: Portopulmonary Hypertension Exception Scores

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

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

extension request that confirms the mean pulmonary arterial pressure (MPAP) remains less than 35 mmHg.

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

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

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

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

Table 9-8: Primary Hyperoxaluria Scores

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

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

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

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) will be provided a score according to *Policy 9.5.I.vii: Extensions of HCC Exceptions* if the candidate that is:

- ~~• At least 18 years old and meets the criteria according to *Policies 9.5.I.i through 9.5.I.vi*. will receive a MELD score according to *Table 9-4: Exception Score Assignment for Candidates at least 18 Years Old at the Time of Registration*~~
- ~~• Twelve to 17 years old, and the Regional Review Board (RRB) has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency, will be listed at a MELD score of 28.~~
- ~~• Less than 12 years old, and the RRB has determined that the candidate's calculated PELD score does not reflect the candidate's medical urgency.~~

9.5.I.i Initial Assessment and Requirements for HCC Exception Requests

Prior to applying for a standardized MELD or PELD exception, the candidate must undergo a thorough assessment that includes *all* of the following:

1. An evaluation of the number and size of lesions before local-regional therapy that meet Class 5 criteria using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. A CT of the chest to rule out metastatic disease
3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
4. An indication that the candidate is not eligible for resection
5. An indication whether the candidate has undergone local-regional therapy
6. The candidate's alpha-fetoprotein (AFP) level

The transplant hospital must maintain documentation of the radiologic images and assessments of all OPTN Class 5 lesions in the candidate's medical record. If growth criteria are used to classify a lesion as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging, and measurements of the lesion.

For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN Contractor within 60 days of transplant. If the pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in a one-year period are not supported by the required pathologic confirmation or submission of clinical information.

9.5.1.ii Eligible Candidates Definition of T2 Lesions

Candidates with T2 HCC lesions are eligible for a standardized MELD or PELD exception if they have an alpha-fetoprotein (AFP) level less than or equal to 1000 ng/mL and *either* of the following:

1. One lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
2. Two or three lesions each greater than or equal to 1 cm and less than or equal to 3 cm in size.

A candidate who has previously had an AFP level greater than 1000 ng/mL at any time must qualify for a standardized MELD or PELD exception according to *Policy 9.5.1.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000*.

9.5.1.iii Lesions Eligible for Downstaging Protocols

Candidates are eligible for a standardized MELD or PELD exception if, before completing local-regional therapy, they have lesions that meet *one* of the following criteria:

1. One lesion greater than 5 cm and less than or equal to 8 cm
2. Two or three lesions each greater than 3 cm or less than or equal to 5 cm, and a total diameter of all lesions less than or equal to 8 cm
3. Four or five lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

For candidates who meet the downstaging criteria above and then complete local-regional therapy, their residual lesions must subsequently meet the requirements for T2 lesions according to *Policy 9.5.1.ii: Eligible Candidates Definition of T2 Lesions* to be eligible for a standardized MELD or PELD exception. Downstaging to meet eligibility requirements for T2 lesions must be demonstrated by CT or MRI performed after local-regional therapy. Candidates with lesions that do not initially meet the downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2

lesions are not automatically eligible for a standardized MELD or PELD exception and must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.iv Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000

Candidates with lesions meeting T2 criteria according to *Policy 9.5.I.ii Eligible Candidates Definition of T2 Lesions* but with an alpha-fetoprotein (AFP) level greater than 1000 ng/mL may be treated with local-regional therapy. If the candidate's AFP level falls below 500 ng/mL after treatment, the candidate is eligible for a standardized MELD or PELD exception as long as the candidate's AFP level remains below 500 ng/mL. Candidates with an AFP level greater than or equal to 500 ng/mL following local-regional therapy at any time must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.v Requirements for Dynamic Contrast-enhanced CT or MRI of the Liver

CT scans and MRIs performed for a Hepatocellular Carcinoma (HCC) MELD or PELD score exception request must be interpreted by a radiologist at a transplant hospital. If the scan is inadequate or incomplete then the lesion will be classified as OPTN Class 0 and imaging must be repeated or completed to receive an HCC MELD or PELD exception.

9.5.I.vi Imaging Requirements for Class 5 Lesions

Lesions found on images of cirrhotic livers are classified according to *Table 9-2*.

Table 9-2: Classification System for Lesions Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study
5A	<ul style="list-style-type: none"> • Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images. • Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase. • <i>Either</i> of the following: <ul style="list-style-type: none"> • Washout during the later contrast phases and peripheral rim enhancement on delayed phase • Biopsy
5A-g	Must meet <i>all</i> of the following: <ol style="list-style-type: none"> 1. Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images. 2. Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase. 3. Maximum diameter increase of at least 50% documented on serial MRI or CT obtained at least 6 months apart.
5B	Must meet <i>all</i> of the following: <ol style="list-style-type: none"> 1. Maximum diameter of at least 2 cm and less than or equal to 5 cm, as measured on late arterial or portal phase images. 2. Increased contrast enhancement, relative to hepatic parenchyma, on late hepatic arterial images. 3. <i>One</i> of the following: <ol style="list-style-type: none"> 1. Washout on portal venous/delayed phase. 2. Peripheral rim enhancement.

Class	Description
	3. Maximum diameter increase, in the absence of ablation, by 50% or more and documented on serial MRI or CT obtained at least 6 months apart. Serial imaging and measurements must be performed on corresponding contrast phases. 4. Biopsy.
5T	Any Class 5A, 5A-g, 5B lesion that was automatically approved upon initial request or extension and has subsequently been ablated.

9.5.I.vii Extensions of HCC Exceptions

In order for a candidate to maintain an approved exception for HCC, the transplant program must submit an updated MELD or PELD Exception Score Request Form ~~every three months~~ that contains the following:

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

The candidate will then receive the additional priority unless *any* of the following occurs:

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

When 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 according to that exception score or the calculated MELD score, whichever is higher.

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

Table 9-9: HCC Exception Scores

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

Exception scores for candidates that were at least 18 years old upon submission of their initial exception request are assigned according to *Table 9-4* below. The candidate's MELD exception score will be capped at 34.

Table 9-4: Exception Score Assignment for Candidates at least 18 Years Old upon Submission of Initial Exception Request

Exception Request	MELD Exception Score
Initial	Calculated MELD score
1 st extension	Calculated MELD score
2 nd extension	28
3 rd extension	30
4 th extension	32
5 th extension and all subsequent extensions	34

A liver candidate less than 18 years old at the time of registration that meets the requirements for a standardized MELD or PELD score exception will be assigned a MELD or PELD score of 40.

To receive the extension, the transplant program must submit an updated MELD/PELD Exception Score Request Form that contains all of the following:

1. An updated narrative
2. Document the tumor using a CT or MRI
3. Specify the type of treatment if the number of tumors decreased since the last request
4. The candidate's alpha-fetoprotein (AFP) level

If a candidate's tumors have been resected since the previous request, then the transplant program must submit an updated MELD/PELD Exception Score Request Form to the NLRB for prospective review.

Candidates with Class 5T lesions will receive a MELD or PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months, without RRB review, even if the estimated size of residual viable tumors falls below stage T2 criteria due to ablative therapy.

9.3.F.viii — Appeal for Candidates not Meeting HCC Criteria

If the NLRB denies the initial HCC MELD/PELD Exception Score Request Form, the transplant program may appeal with the NLRB but the candidate will not receive the additional MELD or PELD priority until approved by the NLRB. The NLRB will refer the matter to the Liver and Intestinal Organ Transplantation Committee for further review and possible action if the NLRB finds the transplant program to be noncompliant with these Policies.

Requests and appeals not resolved by the NLRB within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review. The Liver and Intestinal

~~Organ Transplantation Committee may refer these matters to the MPSC for appropriate action according to Appendix L of the OPTN Bylaws.~~

9.10.A Registration Accuracy

If a member questions the accuracy or appropriateness of a liver allocation or candidate status, the member may report it with reasons for the concern to the ~~host OPO's applicable national liver review board (NLRB) regional review board (RRB)~~. The ~~RRB-NLRB~~ will retrospectively review the allocation or status.

If the ~~RRB-NLRB~~ receives two or more reports about a member within any one year period, the ~~RRB-NLRB~~ will report it to the Membership and Professional Standards (MPSC) Committee and request an on-site review of the member.

9.10.B Review of Status 1A and 1B Candidate Registrations

If ~~the regional review boards reject~~ three or more status 1A or 1B candidate registrations at a transplant program are rejected and each of the candidates receives a transplant while registered at the rejected status, then the OPTN Contractor will conduct an on-site review of the transplant program's status 1A and 1B candidate registrations. If the OPTN Contractor finds a Policy violation or inappropriate registrations, the transplant program will reimburse all necessary and reasonable expenses incurred by the OPTN Contractor in performing this review.

Bylaw Language:

9.3 ~~Regional Review Boards~~

~~Each region establishes regional~~The OPTN establishes review boards (RRBs) for specific organs as necessary to review requests for exceptions that are permitted by Policy. These review boards RRBs provide confidential medical peer review of transplant candidates placed on the waiting list at a more urgent status than the standard listing criteria justifies. As part of these reviews, ~~RRBs review boards~~ may perform the following tasks:

- Review justification forms submitted by the transplant hospital that document the candidate's current condition and decide if the requested status is appropriate.
- Refer transplant hospitals to the appropriate OPTN Committee for review of candidates listed and transplanted at an inappropriate status. The Committee may then, if necessary, refer the hospital to the Membership and Professional Standards Committee (MPSC).
- Serve other peer review functions as determined by the Board of Directors.

~~RRBs~~Review boards are formed for each region under the direction of the Committees and Board of Directors. ~~RRBs~~ Review boards can operate and perform peer review functions as determined by the Board of Directors and considering issues that affect their region. The Board of Directors and Committees may establish other guidelines for ~~RRB~~ Review Board organization and function as necessary.

~~Voting members of the RRBs include physicians and surgeons who are active in organ transplantation from each transplant program in the region for the relevant organ. Regions with a large number of transplant hospitals may use a rotation schedule for physician and surgeon representation on RRBs. A rotation schedule lets transplant hospitals alternate assigning representatives to the RRB so that each transplant hospital is given an equal opportunity to serve on the RRB.~~

Appendix M: Definitions

Regions

For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the region in which they are located.

The regions are as follows:

Region 1	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
Region 2	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 3	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 4	Oklahoma, Texas
Region 5	Arizona, California, Nevada, New Mexico, Utah
Region 6	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 7	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 9	New York, Western Vermont
Region 10	Indiana, Michigan, Ohio
Region 11	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Waiting List

The list of candidates registered with the OPTN to receive organ transplants. When a donor organ becomes available, the matching system generates a new, more specific list of potential recipients based on the criteria defined in that organ's allocation policy. ~~The criteria include, for example, organ type, geographic local and regional area, genetic compatibility measures, details about the condition of the organ, the candidate's disease severity, and time spent waiting.~~