

OPTN/UNOS Policy Notice

Proposal to Establish a National Liver Review Board

Sponsoring Committee:	Liver and Intestinal Organ Transplantation
Policy/Bylaws Affected:	Policy 9.3 (Score and Status Exceptions), Bylaws 9.3 (Review Boards), and Appendix M (Definitions)
Public Comment:	January 23, 2017 – March 24, 2017
Effective Date:	Pending implementation and notice to Members

Problem Statement

A liver candidate receives a MELD or, if less than 12 years old, a PELD score that is used for liver allocation. The score is intended to reflect the severity of the candidate's disease. When the calculated score does not reflect disease severity, a liver transplant program may request an exception score. Currently there is not a national system that provides similar access to transplant for liver candidates whose calculated MELD or PELD score does not accurately reflect the severity of their disease.

Each region has its own review board that evaluates exception requests submitted by the liver programs in its region. Most regions have adopted independent criteria used to request and approve exceptions for specific diagnoses, commonly referred to as "regional agreements." Some have theorized that regional agreements may contribute to regional differences in exception submission and approval practices, even among regions with similar deceased donor organ availability and candidate demographics.

Additionally, there are problems associated with the way in which exception points are currently awarded. Currently, the MELD or PELD exception score for many standardized exception diagnoses increases every three months so long as the candidate continues to meet criteria in Policy. This is problematic for several reasons. The waitlist mortality for non-exception candidates actually exceeds the mortality for exception candidates. Non-exception candidates are also transplanted at higher MELD or PELD scores than those with approved exceptions. Some have suggested that this has contributed to the escalation in MELD or PELD score at transplant that has occurred over the past decade.

The current system also has inefficiencies that can lead to delays in candidates being awarded exception points, as well as excess work for review board members. Regional review board Chair review has been used as an alternative to programming these exceptions for auto-approval in UNetSM. This means that Chairs must manually review over 1,000 standardized exception requests each year which they subsequently approve because candidates meet criteria in Policy.

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.

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* and will be available as part of the implementation of this proposal. In order to automate approval of the standardized exceptions, liver programs will have to submit required information in discrete data fields in UNet instead of in narrative form as they do currently.

Liver programs will also need to be aware and educate staff on the new scoring for standardized exceptions requests.

Affected Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

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 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.

9.4 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).

9.34.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.

9.34.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.~~

9.34.GC MELD or /PELD Score Exception Extensions

~~Transplant hospitals may apply for submit a MELD or PELD score exception extension MELD/PELD Exception Score Request Form to the NLRB to receive the equivalent of a 10~~

percentage point increase in candidate mortality every 90 days, 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 the extension application request more than between 3 and 30 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 then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

9.35-G Specific Standardized MELD/ or PELD Score Exceptions

Candidates meeting the criteria in **Error! Reference source not found.** 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.

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)	All of the following: 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.

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in Policy 9.1.A: <i>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> 1. Clinical evidence of portal hypertension. 2. Evidence of a shunt. 3. PaO ₂ 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 Error! Reference source not found.</i>	<i>See Policy Error! Reference source not found.</i>
Portopulmonary Hypertension	The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention. The diagnosis must also include <i>all of the following:</i> 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 ⁻⁵ .	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.

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
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 or PELD 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*

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:
 - 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. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and 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 liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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 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 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 liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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.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 on the waiting list for a heart transplant, 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 liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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 an echocardiogram that meets *both* of the following criteria:

1. Shows that the candidate has an ejection fraction greater than 40 percent every six months
2. Has been performed within 30 days prior to submission of the extension request

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

A candidate will receive a MELD or PELD score exception for HAT if the candidate 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 or PELD score of 40.

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.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 liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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 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 liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered. 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.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score

equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered. 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.

If a candidate has a metabolic disease other than urea cycle disorder or organic academia, 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 9.4.A: MELD or PELD Score Exception Requests*.

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 candidate has a mean pulmonary arterial pressure less than 35 mmHg following intervention, and 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/cm⁻⁵, or less than 5.1 Wood units (WU), on the same test date as post-treatment MPAP less than 35 mmHg

A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant

calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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 perform a repeat heart catheterization every three months 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 candidate 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. 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 liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points above the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.

A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized MELD or PELD score exception will be assigned a score that is 3 points above the median MELD at transplant for all liver recipients in the region where the candidate is registered.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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

9.3.F Candidates with Hepatocellular Carcinoma (HCC)

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

- At least 18 years old with Hepatocellular Carcinoma (HCC) and meets the criteria according to ~~*Policies 9.3.F.i through vi*~~ *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 upon Submission of Initial Exception Request.*~~
- Twelve to 17 years old, and the ~~Regional~~ National Liver Review Board (NLRRB) 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 ~~NLRB~~ RRB has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency, ~~will be listed at a PELD score of 44.~~

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

Prior to applying for a standardized MELD 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.

9.3.F.ii 9.5.I.ii Eligible Candidates Definition of T2 Lesions

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

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

9.3.F.iii 9.5.I.iii Lesions Eligible for Downstaging Protocols

Candidates are eligible for inclusion in a downstaging protocol if they initially present with lesions that meet *one* of the following criteria:

- One lesion greater than 5 cm and less than or equal to 8 cm
- Two or three lesions each less than 5 cm and a total diameter of all lesions less than or equal to 8 cm
- 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 and then complete local-regional therapy, their residual lesions must subsequently meet the requirements for T2 lesions according to *Policy 9.3.F.ii 9.5.I.ii: Eligible Candidates Definition of T2 Lesions* to be eligible for a standardized MELD exception. Downstaging to meet eligibility requirements for T2 lesions must be demonstrated by CT or MRI performed after local-regional treatment. 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 exception and must be referred to the NLRB for consideration of a MELD exception.

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

Candidates with lesions meeting T2 criteria according to *Policy 9.3.F.ii 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, they are eligible for a standardized MELD exception. Candidates with an AFP level greater or equal to 500 ng/mL following local-regional therapy at any time must be referred to the NLRB for consideration of a MELD exception.

9.3.F.v 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.

9.3.F.vi 9.5.I.vi Imaging Requirements for Class 5 Lesions

Lesions found on images of cirrhotic livers are classified according to *Table 9-32*.

Table 9-32: Classification System for Nodules Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study

Class	Description
5A	<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. <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	<p>Must meet <i>all</i> of the following:</p> <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	<p>Must meet <i>all</i> of the following:</p> <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"> a. Washout on portal venous/delayed phase. b. Peripheral rim enhancement. c. 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. d. Biopsy.
5T (Treated)	Any Class 5A, 5A-g, 5B lesion that was automatically approved upon initial request or extension and has subsequently been ablated.

9.3.F.vii-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/PELD Exception Score Request Form every three months. The candidate will receive the additional priority as long as they continue to meet initial eligibility criteria.

A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned the candidate's calculated MELD score upon initially requesting a MELD score exception, and upon submitting the first exception request. For each subsequent request, the candidate will receive a MELD score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD. The median MELD at transplant calculation

excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

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.

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

If a candidate was less than 18 years old upon submission of their initial exception request, the candidate will receive additional MELD or PELD points equivalent to a 10 percentage point increase in the candidate's mortality risk every three months according to *Table 9-5* below.

Table 9-5: First Seven Exception Score Assignments for Candidates less than 18 Years Old upon Submission of Initial Exception Request

Exception Request	MELD or PELD Exception Score
Initial	MELD 28 or PELD 41
1st extension	MELD 30 or PELD 44
2nd extension	MELD 32 or PELD 47
3rd extension	MELD 34 or PELD 50
4th extension	MELD 36 or PELD 53
5th extension	MELD 39 or PELD 56
6th extension	MELD 40 or PELD 60

To receive the an 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 RRB 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~~ ~~9.5.I.viii~~ Appeal for Candidates not Meeting HCC Criteria

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

Requests and appeals not resolved by the RRB 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.

~~9.3.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 9.6 Waiting Time

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

OPTN Bylaws

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

Regional Review Boards (RRBs)

Peer review panels established in each of the 11 regions to review all urgent status listings for liver and heart candidates. The RRB reviews justification forms submitted by each transplant hospital documenting the severity of the candidate's illness and justifies the status at which the candidate is listed. Heart RRBs review exception requests for heart candidates and adult status 1, 2, 3, and 4 heart candidates. These review boards also consider appeals of cases initially refused for a particular medical urgency status.