

Briefing to the OPTN Board of Directors on

Further Enhancements to the National Liver Review Board

OPTN Liver and Intestinal Organ Transplantation Committee

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Further Enhancements to the National Liver Review Board

<i>Affected Policies:</i>	<i>Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions</i> <i>Policy 9.5.I.i: Initial Assessment and Requirements for HCC Exception Requests</i>
<i>Affected Guidelines:</i>	<i>National Liver Review Board Operational Guidelines</i>
<i>Affected Guidance:</i>	<i>Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review</i>
<i>Sponsoring Committee:</i>	<i>Liver and Intestinal Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>August 4, 2020 – October 1, 2020</i>
<i>Board of Directors Date:</i>	<i>December 7, 2020</i>

Executive Summary

The purpose of the National Liver Review Board (NLRB), which was implemented on May 14, 2019, is to provide equitable access to transplant for liver candidates whose calculated model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency.¹ Since implementation, the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) has regularly evaluated the NLRB to identify opportunities for improvement. The first round of enhancements to the NLRB was approved by the OPTN Board of Directors (the Board) on June 8, 2020.² This proposal represents the second round of enhancements based on further experience with the NLRB.

This proposal seeks to make the following enhancements to the NLRB policy, operational guidelines, and guidance documents in order to make the system more efficient and equitable.

- **Policy:** The proposed changes to policy include updating the criteria for a standardized MELD or PELD exception for portopulmonary hypertension (POPH) to match updated clinical guidelines and creating a more effective process for reviewing *Post-Transplant Explant Pathology* forms for candidates with hepatocellular carcinoma (HCC). Changes to data collection are required to operationalize the updates for the POPH criteria.
- **Operational Guidelines:** The improvements to the operational guidelines include creating a separate Appeals Review Team (ART) specifically for pediatric cases and adding an ART leader to each ART.
- **Guidance:** The Committee proposes to update the guidance for polycystic liver disease (PLD) to clarify the MELD score recommendation, provide guidance for candidates also requiring a kidney, and add new comorbidities that should be considered for a MELD exception in conjunction with PLD.

¹ *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

² *Enhancements to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2020, Available at <https://optn.transplant.hrsa.gov/>

The proposal was well supported throughout public comment. In response to the feedback submitted, the Committee is proposing post-public comment changes to the policy language for POPH exception extensions and the process for reviewing *Post-Transplant Explant Pathology Forms* for candidates with HCC, as well as providing more specificity in the operational guidelines for the ART leader.

Background

When being listed for a liver transplant, candidates receive a calculated MELD or PELD score, which is based on a combination of the candidate's clinical lab values.³ These scores are designed to reflect the probability of death on the waitlist within a three-month period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned a priority 1A or 1B status.

When a transplant program believes that a candidate's calculated MELD or PELD score does not accurately reflect a candidate's medical urgency, they may request a score exception. The NLRB is responsible for reviewing exception requests that do not meet standardized criteria and either approving or denying the requested score.

The NLRB was approved by the Board at their June 2017 meeting and was implemented on May 14, 2019.⁴ The NLRB was designed to create an efficient and equitable system for reviewing exception requests for candidates across the country.

The Committee has regularly evaluated the NLRB to identify opportunities for improvement. In fact, the improvements included in this proposal represent the second round of changes to the NLRB. Prior changes were included in the *Enhancements to the NLRB* proposal that was approved by the Board in June 2020.⁵

Purpose

Since the implementation of the NLRB, the Committee has carefully evaluated the effectiveness of the system. The Committee has identified a number of ways in which the NLRB could be improved through updates to the NLRB policy, operational guidelines, and guidance documents. The purpose of this proposal is to build upon previous enhancements and continue to improve the NLRB by incorporating feedback from the transplant community. The proposed changes are anticipated to create a more efficient and equitable system for the review of exception requests.

The enhancements included in this proposal involve changes to OPTN policy language, the operational guidelines, and the guidance documents. The operational guidelines outline the function and operation of the NLRB, including who may participate as an NLRB reviewer, the responsibilities of NLRB reviewers, voting procedures, and the appeal process. The guidance documents are intended to provide guidance to review board members and transplant programs to help ensure consistent and equitable review of exception cases. The guidance documents serve as a resource for reviewers and transplant programs and are not OPTN policy. Each of the three specialty review boards (Pediatric, Adult Other Diagnosis, and Adult HCC) has a specific guidance document. The Committee is proposing changes to the guidance documents for the Adult Other Diagnosis specialty review board.

³ The calculation for the MELD and PELD scores can be found in OPTN Policy, Available at <https://optn.transplant.hrsa.gov/>

⁴ *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

⁵ *Enhancements to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2020, Available at <https://optn.transplant.hrsa.gov/>

The Committee submits the following proposal for Board consideration under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”⁶ This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. The Committee submits the proposal to collect additional data under the authority of the OPTN Final Rule, which states the OPTN shall “maintain records of all transplant candidates, all organ donors and all transplant recipients”⁷ and shall “...receive...such records and information electronically...”⁸

Sentiment from Public Comment

The proposal was out for public comment from August 4, 2020 to October 1, 2020. The proposal was presented at 11 regional meetings and received additional feedback on the OPTN website. The proposal was presented to the Membership and Professional Standards Committee (MPSC), Data Advisory Committee (DAC), and Pediatric Transplantation Committee (Pediatric Committee).

The proposal was well-supported throughout public comment. It was supported by all 11 regions, as well as the American Society of Transplant (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), NATCO, and the Society for Pediatric Liver Transplantation (SPLIT). The MPSC and Pediatric Committee indicated support for the proposal and the DAC specifically supported the proposed new data collection elements.⁹

Public comment sentiment indicated support for this proposal across all 11 OPTN regions, as shown in **Figure 1**.¹⁰

⁶ 42 CFR §121.4(a)

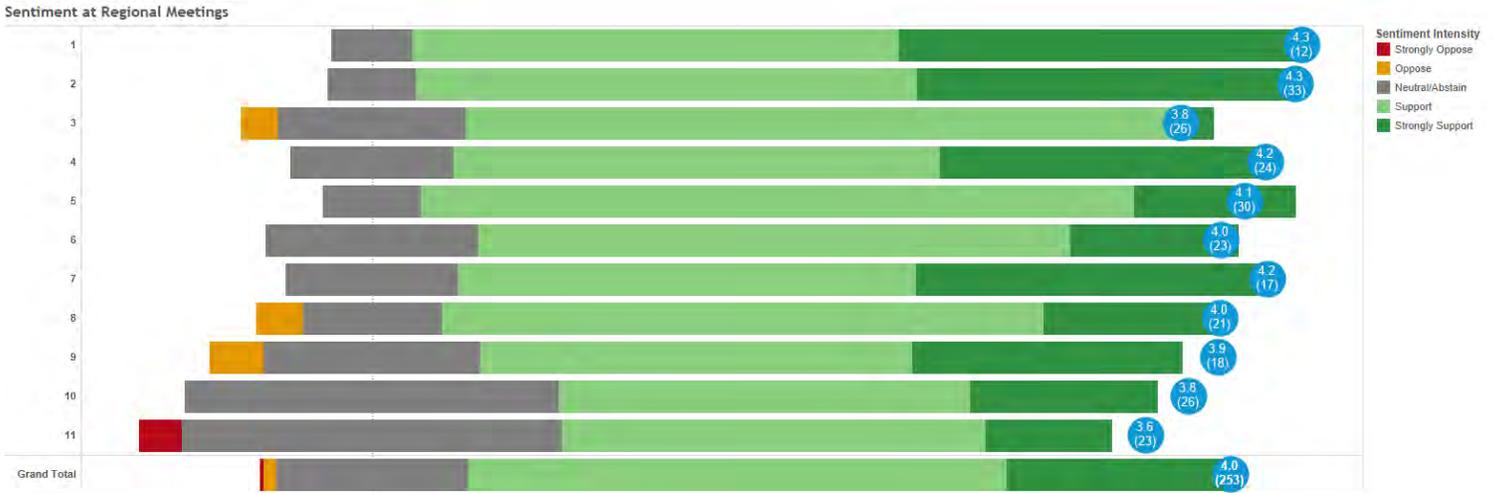
⁷ 42 CFR §121.11(a)(1)(ii)

⁸ 42 CFR §121.11(a)(1)(iii)

⁹ The MPSC provided the following sentiment: 7 strongly support; 23 support; 1 neutral/abstain; 1 oppose; 0 strongly oppose. The Pediatric Committee provided the following sentiment: 9 strongly support; 0 support; 0 neutral/abstain; 0 oppose; 0 strongly oppose

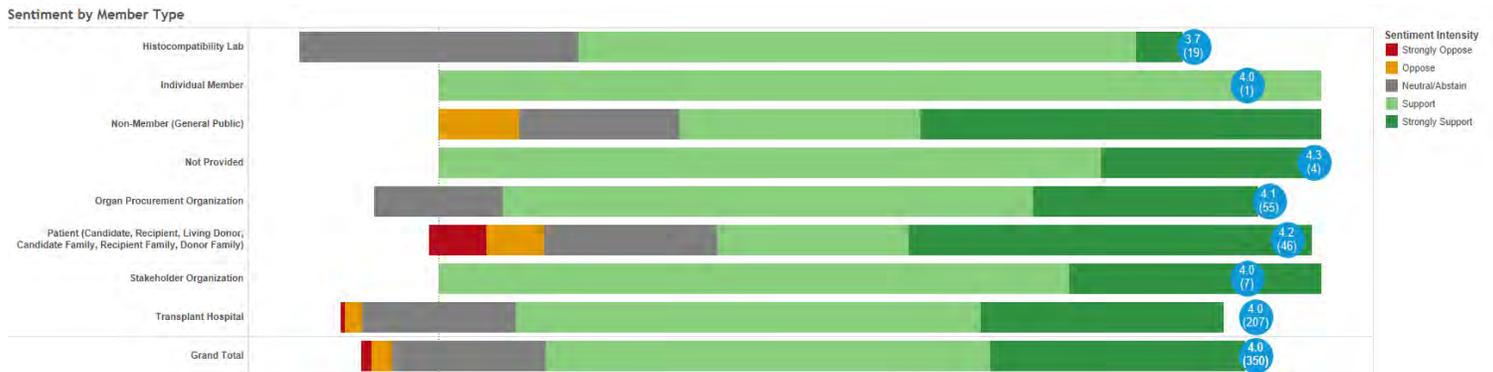
¹⁰ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Figure 1: Sentiment at Regional Meetings



Public comment sentiment by member type is below in **Figure 2**.¹¹

Figure 2: Sentiment by Member Type



While the proposal was well-supported throughout public comment, there are a number of post-public comment changes that the Committee is recommending. In policy, the Committee removed the unnecessary use of the term “post-treatment” in the exception extension criteria for POPH and provided more specificity on the type of treatment for HCC prior to transplantation, as well as clarified some of the language related to the process for reviewing *Post-Transplant Explant Pathology* forms. The Committee is also updating the proposed changes to the Operational Guidelines to include a Pediatric ART leader and more detail on the responsibilities of the ART leader.

It is necessary to note that the majority of the public comments submitted on this proposal related to updating the NLRB guidance for candidates with primary sclerosing cholangitis (PSC) and primary biliary cholangitis (PBC). The Committee has reviewed these comments. The original proposal did not include any changes to the guidance for PSC or PBC, and as a result, the proposal put before the Board does not

¹¹ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

include post-public comment changes to such guidance. The Committee has reviewed updated data on candidates with PSC or PBC and is considering changes to the guidance for these candidates in an upcoming proposal.

Proposal for Board Consideration

The Board is being asked to consider changes to OPTN Policy, NLRB Operational Guidelines, and Guidance in order to create a more efficient and equitable system for reviewing MELD and PELD exception requests.

OPTN Policy

The Committee is proposing two changes to OPTN policy language as part of this proposal. The Committee proposes to update the standardized criteria for initial exceptions and extensions of exceptions for candidates with portopulmonary hypertension (POPH) as outlined in *OPTN Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions* to provide more appropriate standardized exceptions and better meet current clinical guidelines. The Committee is also proposing changes to the process for reviewing *Post-Transplant Explant Pathology Forms* for candidates with hepatocellular carcinoma (HCC) to allow for more effective oversight of programs submitting HCC exceptions.

Updating Standardized Criteria for Portopulmonary Hypertension Exceptions

The initial criteria for MELD or PELD exceptions for candidates with portopulmonary hypertension (POPH) were developed in 2006 as a part of the MELD Exception Study Group and Conference (MESSAGE).¹² These criteria were formally adopted into OPTN policy in 2009.¹³ Since that time, the criteria for candidates with POPH to be automatically approved for an exception have not substantially changed. The Committee intends to update the criteria for candidates to receive a standardized exception as more recent data and guidelines indicate that the current standardized criteria should be revised. The proposed criteria will ensure that the appropriate candidates are eligible for a standardized exception and reduce the burden of the Adult Other Diagnosis specialty board.

Since 2018, there have been 75 deceased donor transplant recipients with POPH. This represents 0.4% of all transplants in that time frame. The majority of transplant recipients with POPH are age 40-64 years (69.3%) and white (69.3%). The majority of these individuals had public insurance (64.4%). Since 2018, 90.1% of all exception forms for POPH have been approved. From the time that the NLRB was implemented, 85 (63.4%) exception forms for POPH met standard criteria and were automatically-approved. Conversely, 48 (35.8%) exception forms did not meet standard criteria and were reviewed by the NLRB and one (0.7%) form met standard criteria and was reviewed by the NLRB. There is not much variation in the number of candidates with POPH on the liver waiting list between OPTN regions.¹⁴ As of October 23, 2020, 15 (20%) of the 75 deceased donor liver transplant recipients during 1/1/2018 –

¹² Michael J. Krowka et al., “Model for End-Stage Liver Disease (MELD) Exception for Portopulmonary Hypertension,” *Liver Transplantation* 12, o. S3 (2006), <https://doi.org/10.1002/lt.20975>

¹³ OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Report to the Board of Directors, June 2009

¹⁴ OPTN Data accessed on June 16, 2020. Data includes all liver transplant recipients from deceased donors during January 1, 2018 through May 31, 2020; all liver waiting list registrations on the waiting list on June 12, 2020; and all liver MELD or PELD exception forms for POPH submitted during January 1, 2018 through May 31, 2020

5/31/2020 with portopulmonary hypertension exception were reported to have experienced a graft failure, and ultimately death, to the OPTN.¹⁵

In order for a candidate to receive a standardized exception for POPH in current policy, the transplant program must submit an initial mean pulmonary arterial pressure (MPAP) and pulmonary vascular resistance (PVR). These values must be taken prior to the initiation of any treatment protocols. Transplant programs must also submit documentation that treatment was administered and that the MPAP and PVR values were improved after treatment. The post-treatment MPAP and PVR values must meet specific thresholds in order for the candidate to be eligible for a standardized exception. The Committee is proposing a number of changes related to the pre-treatment and post-treatment measurements and thresholds of MPAP and PVR.

In the current criteria, there are no specific thresholds for the pre-treatment MPAP or PVR values. While the intent of the policy is to document an improvement from the pre-treatment to the post-treatment values, this is not currently required in the system, as any values can be entered for the pre-treatment measurements. To better document an improvement before and after administration of treatment, the Committee is proposing that candidates must have moderate to severe POPH, as defined by MPAP greater than 35 mmHg and a PVR greater than or equal to 240 dynes*sec/cm⁵ prior to administration of any treatment, in order to be eligible for a standardized exception.¹⁶ These criteria, although not explicit in previous policy, meet established clinical guidelines and should not reduce access to transplantation, as patients with less severe POPH are not considered to be candidates for liver transplantation.¹⁷

The ASTS provided feedback during public comment on the proposed changes to pre-treatment criteria for standardized POPH exceptions. Specifically, the ASTS recommended that the pre-treatment criteria only include a requirement that PVR be greater than 240 dynes*sec/cm⁵, instead of MPAP greater than or equal to 35 mmHg and PVR greater than or equal to 240 dynes*sec/cm⁵. This suggestion was based on the understanding that the diagnostic criteria should include an MPAP greater than 25 mmHg, PVR greater than 240 dynes*sec/cm⁵, and a pulmonary artery occlusion pressure (PAOP) less than 15 mmHg. The Committee reviewed this feedback and determined that the policy put forth as part of the original proposal remained appropriate, as pre-treatment MPAP greater than or equal to 35 mmHg is supported by the current clinical guidelines and is a necessary value in determining moderate to severe POPH.¹⁸

The Committee is also proposing changes to the post-treatment MPAP and PVR thresholds. In current policy, a candidate must have a post-treatment MPAP value less than 35 mmHg and a PVR value less than 400 dynes*sec/cm⁵. The Committee is proposing additional criteria to also allow a candidate to be automatically approved for an exception if treatment results in an MPAP value between 35 mmHg and 45 mmHg with corresponding improvement of PVR to be less than 240 dynes*sec/cm⁵. **Table 1** below summarizes the proposed changes to the post-treatment hemodynamic criteria:

¹⁵ This information does not represent a survival rate, as the survival rate cannot be calculated as a ratio of these numbers.

¹⁶ Michael J. Krowka et al., "International Liver Transplant Society Practice Guidelines: Diagnosis and Management of Hepatopulmonary Syndrome and Portopulmonary Hypertension," *Transplantation* 100, no. 7 (2016): pp. 1440-1452, <https://doi.org/10.1097/tp.0000000000001229>

¹⁷ Ibid.

¹⁸ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

Table 1: Post-treatment Hemodynamic Criteria

Current Post-Treatment Hemodynamic Criteria	Proposed Post-Treatment Hemodynamic Criteria
1. If MPAP is less than 35 mmHg then PVR must be less than 400 dynes*sec/cm ⁵	1. If MPAP is less than 35 mmHg then PVR must be less than 400 dynes*sec/cm ⁵ OR 2. If MPAP is greater than or equal to 35 and less than 45 mmHg then PVR must be less than 240 dynes*sec/cm ⁵

Published research suggests the need to update the post-treatment criteria to better capture the candidate population suitable for a standardized exception. MPAP is calculated by the following equation, which includes cardiac output (CO) and pulmonary artery wedge pressure (PAWP): $MPAP = CO \times PVR + PAWP$. The current post-treatment criteria do not account for the different causes of an elevated MPAP, which include an increase in PVR associated with pulmonary vasoconstriction and vascular remodeling, as well as patients with a high CO or volume overload.¹⁹ In addition, the current post-treatment threshold of 35 mmHg is based on a single-center observational study and literature review of 43 patients transplanted with POPH prior to 2000 and a multi-center database of 66 POPH patients, 26 of whom were transplanted prior to 2001.^{20, 21}

Recent research describes positive post-transplant outcomes in patients with an MPAP greater than 35 mmHg caused by an increase in CO and a normal PVR, which commonly occurs in patients who have received treatment.^{22, 23} However, no patient with a hyperdynamic circulatory state had an MPAP greater than 45 mmHg.²⁴ Additional research indicates that PVR, and not MPAP, is a strong predictor of waitlist mortality in transplant candidates with POPH.²⁵ Finally, only 5.4 % of hepatologists and pulmonary hypertension physicians who responded to a recent survey felt that an MPAP greater than 35 mmHg should be considered as an absolute contraindication to liver transplantation.²⁶

Based on the available evidence, the Committee is proposing an update to the post-treatment criteria to allow for a standardized exception when MPAP is less than 35 mmHg and PVR is less than 400 dynes*sec/cm⁵, and also when MPAP is greater than or equal to 35 mmHg and less than 45 mmHg and PVR is less than 240 dynes*sec/cm⁵.

¹⁹ Michael J. Krowka et al., “International Liver Transplant Society Practice Guidelines: Diagnosis and Management of Hepatopulmonary Syndrome and Portopulmonary Hypertension,” *Transplantation* 100, no. 7 (2016): pp. 1440-1452, <https://doi.org/10.1097/tp.0000000000001229>

²⁰ Michael J. Krowka et al., “Pulmonary Hemodynamics and Perioperative Cardiopulmonary-Related Mortality in Patients With Portopulmonary Hypertension Undergoing Liver Transplantation,” *Liver Transplantation* 6, no. 4 (2000): pp. 443-450, <https://doi.org/10.1053/jlts.2000.6356>

²¹ Michael J. Krowka et al., “Hepatopulmonary Syndrome and Portopulmonary Hypertension: A Report of the Multicenter Liver Transplant Database,” *Liver Transplantation* 10, no. 2 (2004): pp. 174-182, <https://doi.org/10.1002/lt.20016>

²² Erin S. DeMartino et al., “Frequency and Outcomes of Patients With Increased Mean Pulmonary Artery Pressure at the Time of Liver Transplantation,” *Transplantation* 101, no. 1 (2017): pp. 101-106, <https://doi.org/10.1097/tp.0000000000001517>

²³ Corey J. Sadd et al., “Long-Term Outcomes and Survival in Moderate-Severe Portopulmonary Hypertension After Liver Transplant,” *Transplantation* Publish Ahead of Print (2020), <https://doi.org/10.1097/tp.0000000000003248>.

²⁴ Erin S. DeMartino et al., “Frequency and Outcomes of Patients With Increased Mean Pulmonary Artery Pressure at the Time of Liver Transplantation,” *Transplantation* 101, no. 1 (2017): pp. 101-106, <https://doi.org/10.1097/tp.0000000000001517>

²⁵ Hilary M. Dubrock et al., “Predictors of Waitlist Mortality in Portopulmonary Hypertension,” *Transplantation* 101, no. 7 (2017): pp. 1609-1615, <https://doi.org/10.1097/tp.0000000000001666>

²⁶ Hilary M. Dubrock et al., “Portopulmonary Hypertension: a Survey of Practice Patterns and Provider Attitudes,” *Transplantation Direct* 5, no. 6 (2019), <https://doi.org/10.1097/txd.0000000000000900>

In public comment, the ASTS proposed removing the 400 dynes*sec/cm⁵ threshold for candidates with MPAP less than 35 mmHg in the post-treatment criteria. The ASTS commented that all candidates should have a post-treatment PVR less than 240 dynes*sec/cm⁵, as this would preclude candidates that have fixed pulmonary hypertension who do not respond to vasodilator therapy and do not benefit from transplantation. The Committee considered this feedback, reviewed available data, consulted with subject matter experts, and determined that the 400 dynes*sec/cm⁵ threshold for candidates with MPAP less than 35 mmHg in the post-treatment criteria should remain.²⁷

The intent of the revised criteria is to allow candidates who respond well to treatment, and subsequently have an improved PVR (less than 240 dynes*sec/cm⁵), but who continued to have a high MPAP (greater than or equal to 35 mmHg and less than 45 mmHg) due to a high cardiac output, to be eligible for a standardized MELD exception. The Committee determined that the change proposed by ASTS would actually be more restrictive than current policy and there is not sufficient data to show that candidates meeting the current criteria have poor outcomes.²⁸

In response to the comments from ASTS, the Committee reviewed individual data in two publications.^{29,30} In the two studies, 33 of the 124 liver transplant patients with POPH would not have met the standardized criteria suggested by ASTS due to having a PVR greater than 240 dynes*sec/cm⁵. Of the 33 patients with PVR greater than 240 dynes*sec/cm⁵, three (9%) had a transplant hospitalization death and 30 (91%) had positive transplant outcomes. The Committee also reviewed data from a to-be-published study based on the recent experience at the Mayo Clinic.³¹ In this data, eight liver transplant patients had a PVR greater than 240 dynes*sec/cm⁵. Three of these patients suffered a transplant hospitalization death and all others had longer term survival. Based on this data, the Committee decided not to incorporate the suggested changes from the ASTS.

In addition to the changes to the pre-treatment and post-treatment thresholds, the Committee is also proposing the addition of policy language indicating that the pre-treatment values must be from the same test date. This language already exists for the post-treatment criteria and will ensure that the data entered represents the candidate's clinical condition at a single point in time. The proposed language also includes the requirement that the values are obtained via right heart catheterization. This is intended to match the requirements for POPH exception extensions and ensures that the values are collected via the clinically appropriate means.

The Committee is proposing new policy language requiring transplant programs to indicate that other causes of pulmonary hypertension have been assessed and determined not to be a significant contributing factor to the clinical situation of the candidate. International Liver Transplant Society (ILTS)

²⁷ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

²⁸ See OPTN Liver and Intestinal Organ Transplantation Committee, National Liver Review Board Subcommittee, meeting summary, October 13, 2020. Available at <https://optn.transplant.hrsa.gov/>

²⁹ Marius M Hoepfer, Michael J Krowka, and Christian P Strassburg, "Portopulmonary Hypertension and Hepatopulmonary Syndrome," *The Lancet* 363, no. 9419 (2004): pp. 1461-1468, [https://doi.org/10.1016/s0140-6736\(04\)16107-2](https://doi.org/10.1016/s0140-6736(04)16107-2).

³⁰ Michael Krowka, "Pulmonary Hemodynamics and Perioperative Cardiopulmonary-Related Mortality in Patients With Portopulmonary Hypertension Undergoing Liver Transplantation," *Liver Transplantation* 6, no. 4 (2000): pp. 443-450, <https://doi.org/10.1053/jlts.2000.6356>.

³¹ Rodrigo Cartin-Ceba et al., "Clinical Outcomes after Liver Transplantation in Patients with Portopulmonary Hypertension," *Transplantation Ahead of Print*, n.d., <https://doi.org/10.1097/TP.0000000000003490>.

Practice Guidelines indicate that other causes of pulmonary hypertension may be present in the setting of liver disease and should not be considered as an indication for liver transplantation.³² Requiring documentation that the candidate does not have another form of pulmonary hypertension will ensure that only those candidates with POPH, who may benefit from liver transplantation, are eligible for a standardized MELD or PELD exception.

This proposed change to policy involves new data collection. Transplant programs will need to indicate on the MELD or PELD exception form for POPH whether or not other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor. More details on the proposed data collection can be found in the section titled, “New Data Collection” below.

The Committee is also proposing the addition of language requiring transplant programs to provide documentation of portal hypertension at the time of the initial exception for candidates to be automatically approved for a POPH exception. There is currently no minimum liver disease severity required for a candidate to receive a standardized POPH exception. Research indicates that severity of liver disease is an important predictive indicator for positive post-transplant outcomes.³³ Patients with less severe liver disease have low mortality and therefore should not be eligible to receive a standardized MELD or PELD exception for POPH.³⁴ Requiring transplant programs to provide documentation of portal hypertension will ensure that only candidates with significant liver disease automatically receive the additional priority.

This proposed change also involves additional data collection. Transplant programs will need to indicate on the exception form if documentation of portal hypertension at the time of the initial exception is available. More details on the proposed data collection can be found in the section titled, “New Data Collection” below.

In addition to the proposed changes to the criteria for an initial MELD or PELD exception, the Committee intends to update the exception extension criteria. Currently, in order for a candidate with an approved POPH exception to automatically maintain the exception, the transplant program must provide evidence of a right heart catheterization since the previous exception or extension that confirms the MPAP remained less than 35 mmHg. The proposed language changes the extension criteria to match the post-treatment hemodynamic criteria for an initial exception. Instead of only requiring transplant programs to document that the MPAP remains less than 35 mmHg, the proposed language would require transplant programs to document that the candidate continues to meet the post-treatment MPAP and PVR criteria previously described for an initial exception. This change ensures that the candidates receiving a standardized extension are continuing to meet the necessary clinical indicators.

This change includes additional data collection. More details on the proposed data collection can be found in the section titled, “New Data Collection” below.

³² Michael J. Krowka et al., “International Liver Transplant Society Practice Guidelines: Diagnosis and Management of Hepatopulmonary Syndrome and Portopulmonary Hypertension,” *Transplantation* 100, no. 7 (2016): pp. 1440-1452, <https://doi.org/10.1097/tp.0000000000001229>.

³³ Maud Reymond et al., “Does Portopulmonary Hypertension Impede Liver Transplantation in Cirrhotic Patients? A French Multicentric Retrospective Study,” *Transplantation* 102, no. 4 (2018): pp. 616-622, <https://doi.org/10.1097/tp.0000000000001981>.

³⁴ Ibid.

In reviewing the proposed policy language, the Committee noticed that the new extension criteria inadvertently included two uses of the term “post-treatment” in reference to the PVR thresholds. The Committee determined that the PVR values entered on the extension form, by definition, must be post-treatment, as programs are required to indicate treatment as part of the initial exception. Therefore, the Committee removed the use of “post-treatment” in the proposed policy language.

Overall, these proposed changes were well-supported throughout public comment. The Committee considered the relevant feedback and decided that only minimal post-public comment changes were warranted.

HCC: Post-Transplant Explant Pathology Form Review

OPTN Policy 9.5.1.i: Initial Assessment and Requirements for HCC Exception Requests outlines the process for reviewing *Post-Transplant Explant Pathology Forms* for candidates with HCC. The purpose of the review process is to ensure that recipients who are transplanted with the additional priority afforded to HCC exception candidates had an accurate diagnosis of HCC. Due to the diagnostic methods for HCC, there may be cases where a transplant program incorrectly identifies a mass on a liver as HCC, and upon resection, realizes that the original mass was not HCC.

Under the process described in current policy, a transplant program is required to submit the explant pathology form to the OPTN within 60 days after a candidate with an HCC exception is transplanted. If the explant pathology form does not indicate evidence of HCC, then the transplant program is required to submit additional documentation or imaging studies to the OPTN confirming HCC at the time that the initial exception request was submitted. The Committee will then review the documentation submitted by a transplant program when 10 percent or more of cases within a one year period are not supported by the required pathologic documentation or other submitted clinical information.

However, this process requires UNOS staff to interpret the additional documentation or imaging studies in order to know when the 10% threshold is met. UNOS staff do not have the clinical expertise to review such documentation. More so, the process requires transplant programs to submit additional documentation when the explant pathology form indicates no evidence of HCC, regardless of whether the candidate has received treatment of HCC. In many instances, there may be no evidence of HCC if the candidate has received treatment for HCC.

The Committee is proposing two changes to the process for reviewing explant pathology forms. The purpose for the changes is to ensure that the Committee has sufficient and appropriate oversight over transplantation of candidates with HCC so that no program is habitually transplanting candidates without evidence or treatment of HCC.

First, the updated policy language would require transplant programs to submit additional documentation only when the explant pathology form does not show evidence of HCC or treatment of HCC. This change reflects the fact that a liver recipient can have no evidence of HCC at the time of transplant due to previous treatment for HCC. Therefore, this change restricts the submission of additional documentation to only those cases where it is not evident that the candidate had HCC and better limits Committee review to those cases where additional oversight is warranted.³⁵

³⁵ Since 2012, 20 transplant programs have had at least 10% of explant pathology forms in a calendar year period with no evidence of HCC and no treatment of HCC. However, in the same time period, 212 transplant programs have had at least 10% of explant pathology forms in a calendar year period with no evidence of HCC.

The proposed changes to the policy will also remove the need for UNOS staff to interpret the submitted documentation or imaging studies. Under the proposed process, when an explant pathology form does not indicate evidence or treatment of HCC, the transplant program will still be required to submit additional documentation to the OPTN, but this documentation will only be reviewed by the Committee if 10% or more of explant pathology forms show no evidence or treatment of HCC in a one year period.

When a transplant program meets the 10% threshold, UNOS staff will de-identify and collate the documentation or imaging studies submitted by the transplant program and facilitate review by the Committee. The Committee will review the documentation to determine if it supports the initial HCC diagnosis or if any candidates were inappropriately transplanted with HCC priority. As a result of the review, the Committee may determine that no further action is needed or they may refer the case to the MPSC. The purpose of referring programs to the MPSC, and the review process in general, is to identify those programs that may be acting in bad faith, as opposed to those programs who believed, in good faith, that the candidate had HCC at the time of initial exception.

The MPSC provided specific feedback on this aspect of the proposal, noting that it seemed unfair to look retrospectively at the explant pathology, which the member would not have had at the time of initial diagnosis. However, the proposed process is designed to account for this situation. If the transplant program submits that the candidate was not treated for HCC and there was no HCC present upon explantation, the program is then required to submit the documentation or imaging studies used to determine the presence of HCC at the time of original diagnosis. Therefore, no transplant program will be penalized for cases where the explant pathology alone does not show evidence or treatment of HCC. It is only when the submitted documentation, which was available to the transplant program at the time of the initial diagnosis, does not support an HCC diagnosis, that the program could be referred to the MPSC.

In addition, the MPSC requested that the policy language explicitly state that the Liver Committee may refer members to the MPSC as a result of this review process. However, the Liver Committee has the authority to refer members to the MPSC as outlined in Appendix L of the OPTN Bylaws and this language is not needed in policy.³⁶

The MPSC also suggested that the Committee consider what metrics they may need to consider for referring members to the MPSC and what they would like to achieve by referring members to the MPSC. The Committee reminds the MPSC that the 10% threshold included in the policy is only to flag those programs that require further review. If a program meets the 10% threshold, it does not mean that the program will be referred to the MPSC in every instance, only that the Liver Committee will review the submitted documentation. After reviewing the submitted documentation, the Liver Committee may then decide to refer a program to the MPSC.

The ASTS asked for further clarification in the policy language as to what constitutes “evidence of HCC treatment prior to transplantation” and if it only includes liver-directed therapy or systemic therapy and checkpoint inhibitors. The Committee agreed that further clarification was warranted and updated the policy language to make it clear that the treatment should be liver-directed therapy. In addition, the Committee made minor, clarifying changes to the policy language to better align with the proposed review process.

³⁶ Current OPTN Bylaws are available at <https://optn.transplant.hrsa.gov/>

Operational Guidelines

The Committee is proposing two changes to the *National Liver Review Board Operational Guidelines*. The operational guidelines outline how the NLRB functions and provides additional detail on the operation of the NLRB.³⁷

Pediatric Appeals Review Team (ART)

Under the current appeal process, a transplant program can appeal a denied case, first to the same group of reviewers, then to the ART, and finally to the Committee. The current ART consists of nine NLRB members, who are assigned to participate on the ART for a one month term. Of the nine NLRB members on each ART, two are from the NLRB Pediatric specialty board. The ART reviews cases via teleconference at a set day and time each week. Representatives from the petitioning transplant program have the ability to join the ART calls and present the case on behalf of the candidate. Five members of the ART must participate on each call and the appeal must achieve a majority plus one affirmative votes in order to be approved.

The Committee is proposing the creation of a pediatric-specific ART to review all cases appealed from the Pediatric specialty board. The pediatric ART would consist only of NLRB reviewers from the Pediatric specialty board, allowing for those individuals with more specific pediatric expertise to review the cases for pediatric candidates.³⁸

The creation of a pediatric ART is in response to feedback from the transplant community and Committee members' own experience on the ART. Transplant programs presenting pediatric cases to the ART often felt that the ART, as currently constructed, did not have sufficient pediatric expertise to provide appropriate case review. Similarly, ART members without pediatric expertise frequently noted that they did not have sufficient expertise to review pediatric cases. The Committee feels that establishing a pediatric ART will better align the expertise of ART reviewers with the assigned cases and provide for more equitable case review.

The creation of a pediatric ART will create additional responsibility for NLRB reviewers, especially on the NLRB Pediatric specialty board. The current guidelines state that NLRB reviewers will serve no more than one month on the ART each year. However, due to the number of members on the Pediatric specialty board, these reviewers will need to serve for multiple months on the Pediatric ART. There are typically fewer ART appeals from the Pediatric specialty board, so while Pediatric ART reviewers will serve longer terms, it is unlikely that they will be responsible for reviewing more cases. In approximately the first six months of the NLRB, there were 15 ART cases from the Pediatric specialty board out of 131 total ART cases. Based on this information, the Pediatric ART should expect to review cases on a less frequent basis, although they will still have calls scheduled every week. The calls will be cancelled if there are no cases to review.

This aspect of the proposal was broadly supported throughout public comment and no post-public comment changes were made.

³⁷ Current operational guidelines are available at <https://optn.transplant.hrsa.gov/>

³⁸ Under the current system, if a pediatric candidate has HCC, the case is reviewed by the Pediatric specialty board. To maintain a consistent process, these cases would be reviewed by the pediatric ART as well.

ART Leader

In addition to creating a Pediatric ART, the Committee is also proposing the addition of an ART leader. Throughout the first year of the NLRB, the Liver Committee has found it difficult to evaluate the ART due to the nature of the ART calls. Unlike reviews conducted electronically, ART reviewers provide feedback on cases via teleconference and such feedback is often difficult to evaluate. Votes and comments from reviewers are documented by UNOS staff but this documentation does not provide detail on the conversation during the call. Committee members who served on the ART also felt that the calls would benefit from having an individual designated to help lead the calls and facilitate discussion.

To address these concerns, the Committee is proposing the addition of an ART leader to each ART. In the proposal that went out for public comment, the Committee did not include an ART leader for the Pediatric ART. The Committee's intent was to assign a current member of the Committee to serve as the ART leader each month, and there are typically not enough Committee members with pediatric expertise to serve as the ART leader for the Pediatric ART.

However, public comment feedback was supportive of having a Pediatric ART leader and suggested that members of the Pediatric Committee could serve as the ART leader for the Pediatric ART. Committee members also suggested that prior members of either the Liver or Pediatric Committee could serve as the ART leader for the Pediatric ART. Based on this feedback, the Committee decided to provide more detail in the operational guidelines for the ART leader.

The new language makes it clear that the ART leader for the Adult ART will be a member of the Committee serving on either the Adult Other Diagnosis specialty board or the Adult HCC specialty board. The ART leader for the Pediatric ART will be a member of the Liver Committee or Pediatric Committee serving on the Pediatric specialty board. For both the Adult and Pediatric ART, if there are no current members of the Liver Committee or Pediatric Committee available to serve as the ART leader, prior Committee members or other members of the NLRB can be appointed to serve as the ART leader. The Committee felt that this language made it clear that ART leaders would be current members of either the Liver or Pediatric Committee, but provided enough latitude for other NLRB members to serve if needed. ART leaders will be assigned by UNOS staff based on the updated guidelines, availability, and service history on the ART. This change was reviewed by the leadership of the Pediatric Committee, who supported the updated guidelines.

The Committee also asked for public comment feedback on the specific responsibilities of the ART leader. Based on public comment feedback and further Committee discussion, the updated guidelines state that the responsibilities of the ART leader are to lead ART discussion and provide feedback to the Liver Committee.

Guidance Documents

Each of the three specialty review boards (Pediatric, Adult Other Diagnosis, and Adult HCC) has specific, clinical guidance to assist reviewers in evaluating exception requests for the corresponding candidate population. The guidance documents are intended to provide guidance to transplant programs when submitting exception cases and to review board members when reviewing exception cases. The guidance documents help ensure that cases contain the necessary clinical information and that they are reviewed consistently and equitably. The Committee is proposing changes to the guidance for polycystic

liver disease (PLD), which is in the guidance document for the Adult Other Diagnosis specialty review board.

The current guidance for PLD states that candidates who meet the provided criteria should be considered for a MELD exception such that transplantation is expected within the year. It is difficult for transplant programs to know what exception score to request so that transplantation is expected within the year. More so, reviewers are unable to know if the score requested will allow the candidate to be transplanted within the year, as they do not know any identifying information about the candidate, including the location of the transplant program at which they are registered. This score recommendation has caused confusion for both transplant programs and reviewers. Therefore the Committee intends to change the score recommendation to be more in line with other areas of guidance by recommending that candidates meeting the provided criteria should be considered for an exception score similar to other policy assigned scores.

The Committee is also proposing the addition of guidance for candidates with PLD who require kidney transplantation. The additional guidance states that candidates meeting the criteria for a PLD exception who also meet the medical eligibility criteria for simultaneous liver-kidney allocation as described in *OPTN Policy 9.9: Liver-Kidney Allocation* and are registered on the kidney waitlist should be considered for a MELD exception similar to hyperoxaluria in OPTN policy. This score recommendation is higher than the score recommendation for candidates with PLD who do not require a kidney. The Committee decided to include a higher score recommendation for candidates also requiring a kidney for two reasons. First, the Committee felt that it was appropriate to provide the higher score recommendation to give these candidates a greater likelihood of receiving a liver and a kidney from the same donor. Such a donor would likely be considered high-quality and a high MELD score would be needed to receive an offer for a high-quality donor.³⁹ In addition, candidates with polycystic liver-kidney disease (PCLKD), which are those candidates with PLD also requiring a kidney, who do not have an exception, have higher rates of waiting list removal for death or too sick to transplant than candidates with similar MELD or PELD scores with an exception.⁴⁰ This is specifically true for candidates with a MELD or PELD score higher than 29.⁴¹

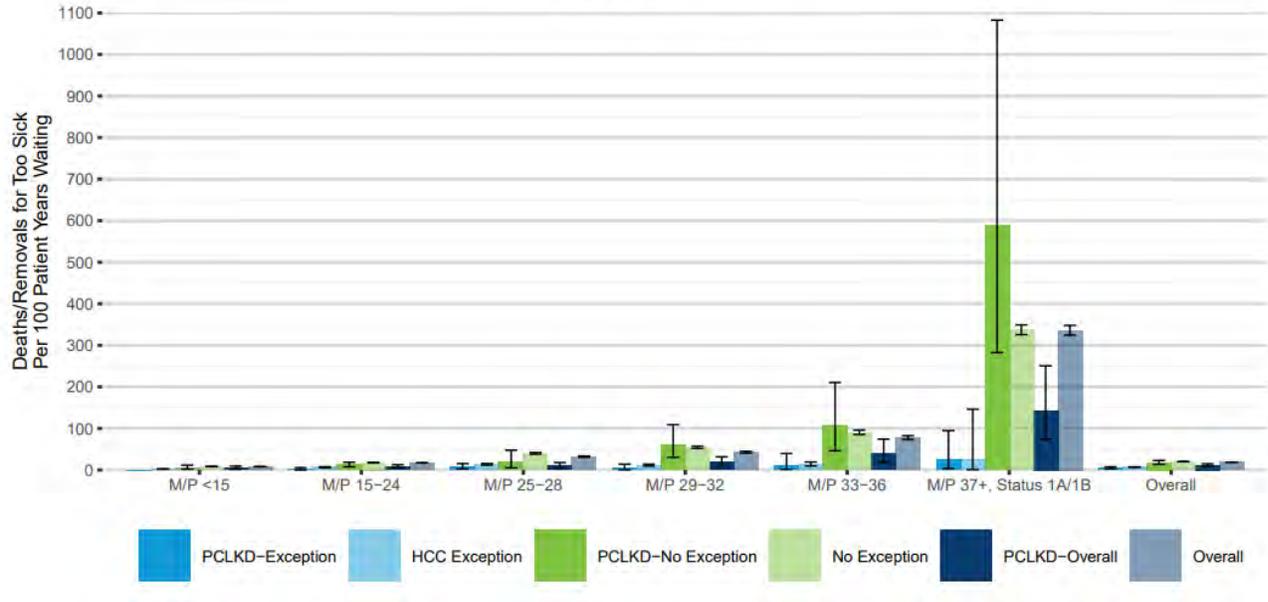
³⁹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, January 9, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁴⁰ Wait list drop out considers the number of candidates removed for death or too sick to transplant divided by the total time patients spent on the waiting list.

⁴¹ OPTN Descriptive Data Request. "Polycystic Liver-Kidney Disease Patients" Prepared for the NLRB Subcommittee Meeting, January 9, 2020.

Figure 3: PCLKD Wait List Drop Out

Liver Waiting List Drop-out Rates Per 100 Patient-Years Waiting, Patients Ever Waiting During 1/01/2014 – 10/31/2019, by PCLKD Diagnosis Classification and Exception Status



In addition, the Committee intends to update the list of comorbidities considered to be appropriate indications for a MELD exception in conjunction with PLD. In the current guidance for PLD, it states that candidates with severe symptoms and either hepatic decompensation, concurrent hemodialysis, or GFR less than 20 ml/min should be considered for a MELD exception. The Committee is proposing that patients with a prior kidney transplant or with moderate to severe protein calorie malnutrition should also be considered for a MELD exception.

The Committee felt that the current guidance inadvertently penalized candidates who previously received a kidney transplant but not a liver graft. These candidates would not have a GFR less than 20 ml/min due to the kidney transplant and would not qualify given the current criteria. However, a candidate needing a kidney and a liver should not lose prioritization for the liver if they previously received only a kidney.⁴² The Committee also intends to include candidates who have moderate to severe protein calorie malnutrition in the list of comorbidities. Often, candidates with PLD have large livers, which restricts their ability to consume nutrition and increases their urgency for transplant.^{43, 44}

The Committee received public comment feedback that “moderate to severe protein calorie malnutrition” should be more objectively defined. The Committee discussed more objective measures

⁴² See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 14, 2019. Available at <https://optn.transplant.hrsa.gov/>

⁴³ Joost P.h. Drenth et al., “Medical and Surgical Treatment Options for Polycystic Liver disease1,” *Hepatology* 52, no. 6 (2010): pp. 2223-2230, <https://doi.org/10.1002/hep.24036>.

⁴⁴ Hyunjin Ryu et al., “Total Kidney and Liver Volume Is a Major Risk Factor for Malnutrition in Ambulatory Patients with Autosomal Dominant Polycystic Kidney Disease,” *BMC Nephrology* 18, no. 1 (2017), <https://doi.org/10.1186/s12882-016-0434-0>.

but ultimately determined that moderate to severe protein calorie malnutrition is the most appropriate addition to the guidance.

NOTA and Final Rule Analysis

The Committee submits the proposed changes to liver allocation policy (*Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions*) for Board consideration under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”⁴⁵ The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.” This proposal:

- **Is based on sound medical judgment**⁴⁶ because it is an evidenced-based change relying on the following evidence:
 - Literature, OPTN data, and medical judgement showing that standardized POPH criteria should be updated to match recent clinical guidelines
- **Seeks to achieve the best use of donated organs**⁴⁷ by ensuring organs are allocated and transplanted according to medical urgency.
 - This proposal seeks to achieve the best use of donated organs by ensuring that only those candidates meeting established clinical criteria are able to receive standardized POPH exceptions.
 - The proposed changes to the process for reviewing *Post-Transplant Explant Pathology* forms for HCC candidates ensure that only those candidates needing the additional priority are awarded an HCC exception score.
- **Is designed to...promote patient access to transplantation**⁴⁸ by giving similarly situated candidates equitable opportunities to receive an organ offer.
 - This proposal is designed to promote patient access to transplantation by allowing candidates meeting established clinical criteria to be eligible for a standardized POPH exception and establishing a better system for ensuring that HCC exceptions are only assigned to those candidates with evidence of HCC.

This proposal is not based on the candidate’s place of residence or place of listing. This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential

⁴⁵ 42 CFR §121.4(a).

⁴⁶ 42 CFR §121.8(a)(1).

⁴⁷ 42 CFR §121.8(a)(2).

⁴⁸ *Id.*

recipient,⁴⁹ and it is specific to an organ type, in this case livers.⁵⁰ The Final Rule also requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised. The Committee did not identify any populations that may be treated “less favorably than they would have been treated under the previous policies” if these proposed policies are approved by the Board of Directors. Therefore the Committee does not recommend any specific transition procedures at this time.⁵¹

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs, to avoid futile transplants, ... and to promote the efficient management of organ placement;

Additionally, the OPTN issues the *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review* for the operation of the OPTN.⁵² This guidance will support the operation of the NLRB by assisting the reviewers with evaluating exception requests. The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including “reducing inter-transplant program variance.”⁵³ This guidance document will assist in reducing inter-transplant program variance by facilitating more consistent review of exception cases.

Alignment with OPTN Strategic Plan⁵⁴

Promote the efficient management of the OPTN:

This proposal promotes the efficient management of the OPTN as it seeks to make the NLRB more efficient and equitable.

Implementation Considerations

Member and OPTN Operations

The proposed changes will require programming in UNetSM, additional education, and support from the OPTN.

The changes to the standardized criteria for POPH involve new data collection which is described in more detail in the “New Data Collection” section.

⁴⁹ 42 CFR §121.8(a)(3).

⁵⁰ 42 CFR §121.8(a)(4).

⁵¹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁵² 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.

⁵³ 42 C.F.R. §121.8(b)(4)

⁵⁴ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

Operations affecting Transplant Hospitals

The proposed changes to the standardized criteria for POPH exceptions involve new data collection, and therefore will require additional member action.

Two new fields will be added to the initial exception form for POPH, as well as new data validation and label changes. Three new fields will be added to the exception extension form for POPH and one field will be removed. Transplant programs will need to be familiar with the new data collection and develop processes to provide the necessary data.

In addition to the new data collection, the proposed changes to the explant pathology form review process will require members to submit additional documentation or imaging studies less frequently, as documentation will only be submitted when there is no evidence or treatment of HCC.

Transplant programs will also need to be aware of the pediatric ART and be prepared to speak to a more pediatric-focused audience when appealing cases to the pediatric ART.

Similarly, transplant programs will need to be familiar with the updated guidance for PLD.

Operations affecting Histocompatibility Laboratories

This proposal does not impact the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal does not impact the operations of organ procurement organizations.

Operations affecting the OPTN

OPTN implementation actions for the different components of this proposal are described in order below.

- **Exception form for POPH:** The proposed changes to the standardized criteria for POPH will require programming in UNet. The OPTN will need to alter the MELD or PELD initial exception form for POPH to match the changes to policy. The new pre-treatment MPAP and PVR thresholds will need to be programmed, as well as changing a current data label from “Test Date” to “Heart Catheterization Date.” The data validation for the post-treatment MPAP and PVR values will need to be updated to match the new post-treatment criteria. Two new fields will be added to the form to allow transplant programs to document that other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor and the presence of portal hypertension at the time of initial exception.
- **Exception Extension form for POPH:** The OPTN will also need to update the POPH exception extension form to meet the updated criteria in policy. One field, Peak mean pulmonary arterial pressure level in the past 90 days, will be removed. Three new fields, MPAP, pulmonary artery wedge pressure (PAWP) and cardiac output will be added to the extension form. These fields are identical to the initial exception form and are used to calculate PVR.

- **Explant Pathology Review:** The OPTN will update the process for reviewing explant pathology forms to match the new policy language.
- **Pediatric ART:** The pediatric ART will be programmed into UNet and UNOS staff will be responsible for managing the pediatric ART roster and facilitating the ART meetings.
- **Communication and Education:** The OPTN will also be responsible for communicating the changes to members and updating educational resources.

Potential Impact on Select Patient Populations

This proposal will have an impact on a number of select patient populations.

Candidates with POPH will be impacted by the proposed changes to the standardized criteria for POPH exceptions. It is important to note that the updated criteria will not require any new or additional testing or procedures for these candidates. The Committee does not anticipate any candidates who would have been eligible for a standardized POPH exception to no longer be able to receive a standardized exception.

The new pre-treatment criteria provide specific thresholds for the MPAP and PVR values to ensure that candidate's receiving an exception have moderate to severe POPH, but the Committee does not anticipate that programs would have applied for an exception for a candidate with mild POPH, despite the lack of specific criteria in current policy. Similarly, the Committee expects that requiring transplant programs to provide evidence that other causes of pulmonary hypertension have been assessed and determined not to be a significant contributing factor and evidence of portal hypertension at the time of initial exception should not preclude any candidate who would have previously been eligible for an exception from still being eligible. It is unlikely that a transplant program would have applied for a POPH exception for a candidate without meeting these criteria. These new requirements follow established standards of care and should be documented in the medical record already.⁵⁵

The updated post-treatment and extension criteria should allow for more candidates to be able to receive a standardized exception as candidates with an MPAP greater than 35 will now be eligible for a standardized exception if the PVR is less than 240 dynes*sec/cm⁵.⁵⁶

The creation of a pediatric ART will allow for pediatric appeals to be reviewed by individuals with more pediatric expertise. This change will provide more equitable review of pediatric ART cases. Transplant programs requesting an exception for candidates with PLD will have clearer guidance on an appropriate score to request for their candidate. Also, the addition of specific guidance for candidates with PLD needing a kidney will make it evident that these candidates should be considered for an exception. In addition, the updated language provides guidance for candidates who received a prior kidney transplant or have moderate to severe protein calorie malnutrition. These additions will allow more candidates with PLD to be appropriately considered for a MELD exception.

There is no anticipated negative impact for any patient group.

⁵⁵ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 14, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁵⁶ Ibid.

New Data Collection

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. The new data collection aligns with the OPTN Data Collection Principle to develop transplant, donation, and allocation policies.⁵⁷ The proposed new data collection is not available through other means for the relevant population of candidates and the OPTN is the appropriate body to collect such information.

The Committee consulted with the OPTN Data Advisory Committee (DAC) and UNOS Data Governance staff for feedback and refining the proposed data collection. The DAC reviewed the proposed data elements and data definitions and had no additional feedback. The Committee utilized a data quality checklist to ensure that the proposed data elements are relevant, available, reliable, usable and do not pose an unrealistic administrative burden.

All changes to data collection as part of this proposal are within WaitlistSM and are not subject to OMB approval. The two new fields on the initial form for POPH exceptions will be required. This matches other “Yes/No” fields on initial exception forms for other diagnoses. If a program selects “No,” the candidate will not receive a standardized exception and the case will be reviewed by the NLRB.

Two new data elements will be added to the initial exception form for POPH to match the proposed changes to policy. These two new data elements are included in the **Table 2** below.

Table 2: New Data Collection: Initial POPH Exception

Corresponding Policy Language/Criteria	Data Element	Response Options	Data Definition
Other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor	Have other causes of pulmonary hypertension been assessed and determined not to be a significant contributing factor?	Radio buttons: <ul style="list-style-type: none"> • Yes • No 	Clinical guidelines for the treatment of POPH with liver transplantation indicate that other causes of pulmonary hypertension should be excluded. If other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor, select Yes. If not, select No. Other causes of pulmonary hypertension include but are not limited to: idiopathic pulmonary hypertension, vasculitis (lupus), chronic pulmonary embolism, sickle cell anemia, and left heart failure.
Documentation of Portal Hypertension at the time of initial exception	Is there documentation of portal hypertension at the time of the initial exception?	Radio buttons: <ul style="list-style-type: none"> • Yes • No 	If documentation of portal hypertension at the time of initial exception is available, select Yes. If not, select, No.

The Committee recognizes that the introduction of these data elements increases the data burden on transplant programs submitting POPH exceptions. However, the intent of the data collection is to ensure

⁵⁷ OPTN Data Collection Principles were approved by the OPTN Board of Directors in 2006.

that only those candidates needing the additional MELD or PELD points are automatically approved for the exception and felt that the additional data burden was justified by this intent. The data are readily available in the electronic health record (EHR) for all relevant candidates due to the normal transplant evaluation process and no additional tests will be needed. The Committee attempted to make the data elements as simple and intuitive as possible so that the data can be consistently reported.

In their deliberation, the Committee noted that all candidates being considered for a POPH exception are evaluated by a pulmonologist or cardiologist to ensure that there are no other causes of pulmonary hypertension. This evaluation is documented in the candidate’s medical record. A transplant coordinator completing the exception form will need to find this information in the candidate’s medical record or consult with the attending hepatologist.

Similarly, the Committee noted that documentation of portal hypertension is available for any candidate with POPH needing a MELD or PELD exception. This information will be available in the candidate’s medical record. A transplant coordinator completing the exception form will need to find this information in the candidate’s medical record or consult with the attending hepatologist.

In addition to the new data elements on the initial exception form, three new elements will be added to the exception extension form and one element will be removed. All three of the new data elements are identical to fields on the initial exception form. The intent of the Committee was to match the post-treatment data collection and MPAP and PVR thresholds on the initial exception form. The three new data elements on the exception extension form are included in the **Table 3** below.

Table 3: New Data Collection: POPH Exception Extensions

Corresponding Policy Language/Criteria	Data Element	Response Options	Data Definition
MPAP	Mean Pulmonary Arterial Pressure (MPAP)	Numerical Value (mmHg)	Enter the mean pulmonary arterial pressure in mmHg. The initial mean pulmonary arterial pressure must be between 0 and 150.0 mmHg.
Value is used to calculate PVR	Pulmonary Artery Wedge Pressure (PAWP)	Numerical Value (mmHg)	Enter the pulmonary artery wedge pressure in mmHg. The initial pulmonary artery wedge pressure must be between 0 and 50.0 mmHg.
Value is used to calculate PVR	Cardiac Output	Numerical value (L/min)	Enter the cardiac output in L/min. The initial cardiac output must be between 0.20 and 15.00 L/min.

All of the values are obtained via right heart catheterization, which is already required as part of the extension criteria. Therefore, while programs will be need to submit additional data, no new tests will be required. Transplant programs will just need to provide more information from the right heart catheterization. The current exception extension form has a field for the date that the right heart

catheterization is completed. This field will be used to ensure that the values listed above are collected on the same date, as outlined in the proposed policy.

The field “Peak mean pulmonary arterial pressure (MPAP) level in the past 90 days” is being removed from the exception extension form. This field is no longer relevant with the incorporation of the new hemodynamic criteria and addition of the data elements described above.

New Data Validation

The proposed changes to policy will necessitate the incorporation of new data validation for the lab values provided both before and after treatment on the initial exception form and on the exception extension form. Transplant programs will need to be familiar with the new data validation for the hemodynamic lab values.

Data Label Changes

On the current exception form, transplant programs must provide a test date documenting when the lab values were collected. In accordance with the policy change, the current test date field will now be labelled, “Heart Catheterization Date.” There is no difference in the data that transplant programs must provide. However, they should be familiar with the updated data label.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is no expected fiscal impact for OPOs.

Projected Impact on Transplant Hospitals

There is minimal expected impact on transplant hospitals.

This proposal does not require any new testing and only requires transplant hospital staff to become familiar with the minor changes to the exception submission form as well as the guidance document. Staff time for additional data entry for a very small cohort of patients may increase.

Projected Impact on the OPTN

Policy and Community Relations will continue to be involved in the implementation effort and ongoing monitoring.

The Member Quality and Review Board teams will operationalize and support the process for reviewing Post-Transplant Explant Pathology forms and submitted additional documentation. Review Board staff will also be responsible for managing the Pediatric ART.

A Large IT Implementation effort, estimated at 820 hours, involves system changes for exception requests (initial and exception) for POPH, Post-Transplant Explant Pathology forms, and the creation of a pediatric ART.

Approximately 80 hours annually of implementation effort and ongoing monitoring from Research is anticipated in order to evaluate the proposed changes and provide monitoring reports on *Post-Transplant Explant Pathology forms*. This monitoring is in addition to current monitoring of the National Liver Review Board.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program.”⁵⁸

The proposed language will not change the current routine monitoring of OPTN members. Site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet is consistent with source documentation including all qualifying criteria used for standardized exceptions reported on the MELD or PELD exception or exception extension form.

This proposal includes language that will ensure that the OPTN has sufficient and appropriate oversight over transplantation of candidates with HCC so that no program is consistently transplanting candidates without sufficient documentation of HCC.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”⁵⁹

In addition to those monitoring reports and items previously enumerated in post-implementation evaluation plans related to the NLRB, the UNOS Research Department will analyze relevant outputs in pre vs. post analyses for the additional enhancements.⁶⁰ Such analyses will continue the cadence of previously laid out evaluation plans (up to 36 months post-implementation of the NLRB), or longer if requested by the Committee.

Relevant analyses:

- Number of exception cases for portopulmonary hypertension
 - Overall, by automatic system approval/NLRB board review, case outcome, and by application type

⁵⁸ 42 CFR §121.8(a)(7).

⁵⁹ 42 CFR §121.8(a)(6).

⁶⁰ *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

- Distribution of automatic approval turn-down reasons for portopulmonary hypertension cases (reasons criteria was not met)
- Number of transplant recipients with portopulmonary hypertension exception
- Number of pediatric Appeals Review Team cases
 - Overall and by case outcome
- Number of exception cases for polycystic liver disease/polycystic liver and kidney disease
 - Overall, by case outcome, by application type, and by liver alone/liver-kidney registration status
- Number of transplant recipients with polycystic liver disease/polycystic liver and kidney disease

Additional metrics as requested by the Committee, relevant to the proposed policy and guidance changes.

Conclusion

The NLRB has been in place for over a year and this proposal is the second round of improvements to the new exception review process. The proposed updates to the standardized criteria for POPH exception match updated clinical experience and ensure that the appropriate candidates are eligible for a standardized exception. The changes to the review process for explant pathology forms provides more appropriate oversight of programs submitting HCC exceptions. The creation of the pediatric ART and the use of an ART leader will improve the equity and efficiency with which ART appeals are reviewed. And finally, the changes to guidance for PLD will ensure that these candidates are appropriately considered for a MELD exception.

Together, these changes will improve the NLRB and the overall liver allocation system.

Policy Language, Guidelines, and Guidance

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

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. Document via heart catheterization initial mean pulmonary arterial pressure (MPAP) level greater than or equal to 35 mmHg and initial pulmonary vascular resistance (PVR) level greater than or equal to 240 dynes*sec/cm⁵ (or greater than or equal to 3 Wood units (WU)). These values must be from the same test date.
- ~~2. Initial pulmonary vascular resistance (PVR) level~~
2. Other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor
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~~
5. Document via heart catheterization within 90 days prior to submission of the initial exception either of the following:
 - Post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400 dynes*sec/cm⁵ (or less than 5 Wood units (WU)). These values must be from the same test date.
 - Post-treatment MPAP greater than or equal to 35 mmHg and less than 45 mmHg and post-treatment PVR less than 240 dynes*sec/cm⁵ (or less than 3 Wood units (WU)). These values must be from the same test date.
6. Documentation of portal hypertension at the time of initial exception

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

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

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

37 extension request that confirms ~~the mean pulmonary arterial pressure (MPAP) remains less~~
 38 ~~than 35 mmHg.~~ either of the following:

- 39 • MPAP less than 35 mmHg and PVR less than 400 dynes*sec/cm⁵ (or less than 5
 40 Wood units (WU)). These values must be from the same test date.
- 41 • MPAP greater than or equal to 35 mmHg and less than 45 mmHg and PVR less
 42 than 240 dynes*sec/cm⁵ (or less than 3 Wood units (WU)). These values must be
 43 from the same test date.

44

45 **9.5.1.i Initial Assessment and Requirements for HCC Exception**

46 **Requests**

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

- 49
- 50 1. An evaluation of the number and size of lesions before local-regional therapy
 51 that meet Class 5 criteria using a dynamic contrast enhanced computed
 52 tomography (CT) or magnetic resonance imaging (MRI)
- 53 2. A CT of the chest to rule out metastatic disease
- 54 3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular
 55 involvement
- 56 4. An indication that the candidate is not eligible for resection
- 57 5. An indication whether the candidate has undergone local-regional therapy
- 58 6. The candidate's alpha-fetoprotein (AFP) level

59

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

65

66 For those candidates who receive a liver transplant while receiving additional
 67 priority under the HCC exception criteria, the transplant hospital must submit the
 68 *Post-Transplant Explant Pathology Form* to the OPTN within 60 days of transplant. If
 69 the ~~pathology report~~ *Post-Transplant Explant Pathology Form* does not show
 70 evidence of HCC or liver-directed therapy for HCC, the transplant ~~hospital~~ program
 71 must also submit documentation or imaging studies confirming HCC at the time of
 72 assignment.

73

74 The Liver and Intestinal Organ Transplantation Committee will review ~~a transplant~~
 75 ~~hospital~~ the submitted documentation or imaging studies when more than 10
 76 percent of the HCC cases in a one-year period are not supported by the required
 77 pathologic confirmation or submission of clinical information. *Post-Transplant*
 78 *Explant Pathology Forms* submitted by a transplant program in a one year period do
 79 not show evidence of HCC or liver-directed therapy for HCC.

National Liver Review Board Operational Guidelines

1. Overview

The purpose of the National Liver Review Board (NLRB) is to provide fair, equitable, and prompt peer review of exceptional candidates whose medical urgency is not accurately reflected by the calculated MELD/PELD score. The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency of the candidate as compared to other candidates with the same MELD or PELD score.

The NLRB is comprised of specialty boards, including:

- Adult Hepatocellular Carcinoma (HCC)
- Adult Other Diagnosis
- Pediatrics, which reviews requests made on behalf of any candidate registered prior to turning 18 years old and adults with certain pediatric diagnoses

The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the Chair of the NLRB for a two year term.

2. Representation

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 alternate to the pediatric specialty board. Individuals may serve on more than one specialty board at the same time. 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.

Representatives and alternates serve a one year term. A liver transplant program may appoint the same representative or alternate to serve consecutive terms.

If a transplant hospital withdraws or inactivates its liver program, it may not participate in the NLRB. However, the transplant hospital's participation may resume once it has reactivated its liver program.

3. Representative and Alternate Responsibilities

Prior to each term of service, representatives and alternates are required to sign the *UNOS Confidentiality and Conflict of Interest Statement* and complete orientation training.

Representatives must vote within 7 days on all exception requests, exception extension requests, and appeals. A representative will receive an e-mail reminder after day 3 and day 5 if the representative has an outstanding vote that must be completed. On the eighth day, if the vote has not been completed, then the request will be randomly reassigned to another representative. The original reviewer will receive a notification that the request has been reassigned.

The representative must notify UNOS in UNetSM of an absence, during which the alternateSM will fulfill the responsibilities of the representative.

47 If a representative or alternate does not vote on an open request within 7 days on more than 5% of the
48 cases assigned to that reviewer within a 6 month period, the Chair may remove the individual from the
49 NLRB. If a representative or alternate does not vote because a case is approved and closed before the 7
50 day timeframe expires, it is not considered a failure to vote. A representative or alternate who has been
51 removed for failure to perform the duties required is not eligible to serve again for 3 years.

52
53 If a transplant program exhibits a pattern of non-responsiveness, as evidenced by the removal of two
54 members from the NLRB, the Chair may suspend the program's participation for a period of three months
55 after notifying the program director. Further non-compliance with the review board process may result in
56 cessation of the program's representation on the NLRB until such a time as the transplant hospital can
57 satisfactorily assure the Chair that it has addressed the causes of non-compliance.

58 59 **4. Voting Procedure**

60
61 An exception request is randomly assigned to five representatives of the appropriate specialty board. A
62 representative may vote to approve or deny the request, or ask that the request be reassigned. The
63 request must achieve four out of five affirmative votes in order to be approved. If the request does not
64 achieve the necessary four affirmative votes, it is denied.

65
66 As part of the MELD/PELD Exception program in UNetSM, NLRB members are notified of new cases by
67 email.

68
69 Voting on an exception request is closed either at the end of the appeal period or when no additional
70 votes will change the outcome of the vote, whichever occurs earlier. Members no longer have the ability
71 to vote once a request is closed.

72 73 **5. Appeal Process**

74
75 A liver program may appeal the NLRB's decision to deny an exception request. Patients are not eligible to
76 appeal exception requests. All reviewer comments are available in UNetSM. The NLRB advises programs to
77 respond to the comments of dissenting reviewers in the appeal.

78
79 The same five members that reviewed the original request will review the appeal. The appeal must
80 achieve four out of five affirmative votes in order to be approved. If the appeal does not achieve the
81 necessary four affirmative votes, it is denied. If the appeal is denied, the liver program may request a
82 conference call with the Appeals Review Team (ART).

83
84 If the ART denies the request, the liver program may initiate a final appeal to the Liver and Intestinal Organ
85 Transplantation Committee (Liver Committee). Referral of cases to the Liver Committee will include
86 information about the number of previous referrals from that program and the outcome of those
87 referrals.

88 89 **6. Appeals Review Team (ART)**

90
91 At the beginning of each new service term, nine NLRB members from the Adult Other Diagnosis and Adult
92 HCC specialty boards are ~~randomly~~ assigned to serve each month of the year on the Adult ART and nine
93 NLRB members from the Pediatric specialty board are assigned to serve each month of the year on the
94 Pediatric ART. There may be multiple ARTs, depending on the volume of cases. ~~An NLRB member will be~~

95 ~~selected to serve for no more than one month each year on the ART. The ART meets via conference call~~
 96 ~~at the same day and time each week; however calls may be rescheduled in advance to accommodate~~
 97 ~~federal holidays. Each ART will be scheduled to meet via conference call according to a predetermined~~
 98 ~~schedule.~~

99
 100 ART appeals from the Adult Other Diagnosis and Adult HCC specialty boards will be reviewed by the Adult
 101 ART. ART appeals from the Pediatric specialty board will be reviewed by the Pediatric ART.

102
 103 In the event of a planned absence, the ART member may designate their alternate to serve. The
 104 representative must notify UNOS of this in UNetSM.

105
 106 Five members of the ART must participate in the call. If at least five members do not attend the call, the
 107 appeal will be rescheduled for the following regularly scheduled conference call. If at least five members
 108 do not attend the second attempt to review the appeal, the candidate's exception request is automatically
 109 approved.

110
 111 The appeal must achieve a majority plus one affirmative votes in order to be approved.

112
 113 A representative at the petitioning program may serve as the candidate's advocate. If a representative is
 114 unable to attend the conference call, the program may ask for the appeal to be scheduled for the following
 115 regularly scheduled conference call. If after two attempts a representative is unable to attend the call, the
 116 ART will review the appeal without the program's participation. In the absence of a representative on the
 117 conference call, the program may submit written information for the ART's consideration.

118
 119 A current member of the Liver Committee serving on either the Adult Other Diagnosis specialty board or
 120 Adult HCC specialty board will be appointed to serve as the ART leader for the Adult ART prior to each
 121 service term. A current member of the Liver Committee or current member of the OPTN Pediatric
 122 Transplantation Committee (Pediatric Committee) serving on the Pediatric specialty board will be
 123 appointed to serve as the ART leader for the Pediatric ART prior to each service term. If no current member
 124 of either the Liver Committee or the Pediatric Committee is available to serve as the ART leader, prior
 125 members of each Committee or other members of the NLRB may be appointed to serve as ART leader.
 126 The ART leader will be prepared to lead ART discussion and provide feedback to the Liver Committee.

127
 128 The ART will work with UNOS staff to document the content of the discussion and final decision in
 129 UNetSM.

130 **7. Liver Committee Review**

131
 132 The Liver Committee may delegate review to a subcommittee. If the review is delegated, majority is based
 133 on the size of the subcommittee.

134
 135 Appeals to the Liver Committee will be considered electronically unless at least one member of the Liver
 136 Committee requests a conference call. If the case is discussed on a conference call, quorum is a majority
 137 of the Liver Committee (or the subcommittee, if delegated).

138
 139 The appeal must achieve a majority affirmative votes in order to be approved.

140

Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review

Polycystic Liver Disease (PLD)

Certain patients with PLD may benefit from MELD exception points. Indication for an exception include those with PCLKD (Mayo type D or C) with severe symptoms plus *any* of the following:

- Hepatic decompensation
- Concurrent hemodialysis
- GFR less than 20 ml/min
- Patient with a prior kidney transplant
- Moderate to severe protein calorie malnutrition

Transplant programs should provide the following criteria when submitting exceptions for PLD. The Review Board should consider the following criteria when reviewing exception applications for candidates with PLD.

1. Management of PLD

PLD Classification – Mayo Modification

Types	A	B	C	D
Symptoms	0 - +	++/+++	++/+++	++/+++
Cyst Findings	Focal	Focal	Diffuse	Diffuse
Spared Remnant Volume	≥3	≥2	≥1	<1
PV/HV Occlusion	No	No	No	Yes

2. Surgical Management of PLD

- Indications:
 - a. Types C* and D **and** at least 2 of the following:
 - Hepatic decompensation
 - Concurrent renal failure (dialysis)
 - b. Compensated comorbidities
- Note:** Prior resection/fenestration, alternative therapy precluded.

Patients who meet the criteria above should be considered for a MELD exception similar to other policy-assigned exception scores. ~~for MELD exception points such that transplantation may be expected within the year.~~

When a candidate also meets the medical eligibility criteria for liver-kidney allocation as described in OPTN Policy 9.9: Liver-Kidney Allocation and is registered on the kidney waitlist, the candidate should be

34 considered for a MELD exception score similar to the score assigned to candidates with primary
35 hyperoxaluria in OPTN Policy.