

OPTN/UNOS Public Comment Proposal to Establish a National Liver Review Board

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee

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Proposal to Establish a National Liver Review Board

Affected Policies: Policy 9.3: Score and Status Exceptions, Bylaw 9.3, Regional Review Boards; and Bylaws Appendix M: Definitions.
Sponsoring Committee: Liver and Intestinal Organ Transplantation
Public Comment Period: January 23, 2017 – March 24, 2017

Executive Summary

A liver candidate receives either a priority status or MELD¹ or, if less than 12 years old, a PELD² score that is used for liver allocation. The score is intended to reflect the severity of the candidate's disease. When the calculated score or status does not reflect the candidate's medical urgency, a liver transplant program may request an exception. Currently there is not a national system that provides equitable access to transplant for liver candidates whose status or calculated MELD or PELD score does not accurately reflect the severity of their disease. Instead, each region has its own review board that evaluates exception requests submitted by the liver transplant programs in its region. Most regions have adopted independent criteria used to request and approve exceptions, commonly referred to as "regional agreements." Some have theorized that regional agreements may contribute to regional differences in exception submission and award practices, even among regions with similar organ availability and candidate demographics.^{3,4,5}

The Liver Committee previously distributed a proposal to establish a national liver review board (NLRB) in January 2016.⁶ Through policy and revised operational guidelines, this proposal incorporates feedback received during the first round of public comment to establish a national structure for review of MELD and PELD exception cases. The NLRB seeks to mitigate regional differences in award practices by establishing new voting procedures and giving the Committee the ability to develop national guidance for assessing common requests, which supports Goal 2 of the OPTN Strategic Plan.⁷ This proposal also improves the efficiency of the review board system by reducing the overall workload for reviewers and eliminating unnecessary delays in awarding exception points when appropriate.

Finally, this proposal modifies the way in which the value for exception points is determined and assigned. To achieve more nationwide uniformity in the value of exception scores awarded to candidates for standardized exceptions, the Committee proposes setting the points assigned to adult candidates to a fixed value just below the median MELD at transplant for adult recipients within the Donation Service Area (DSA). For candidates between 12 to 17 years old, the points value would be tied to the median MELD at transplant for all liver recipients in the DSA. And for pediatric candidates less than 12, the points value would be tied to the median MELD at transplant for all liver recipients in the region. This change serves a secondary goal of addressing the ever-increasing rise in median MELD at transplant, otherwise known as MELD inflation.

¹ Model for End-Stage Liver Disease

² Pediatric End-Stage Liver Disease

³ Argo, C. K., G. J. Stukenborg, T. M. Schmitt, et al. "Regional Variability in Symptom-Based MELD Exceptions: A Response to Organ Shortage?" *American Journal of Transplantation*, 11(2011), 2353-2361.

⁴ Massie, A. B., B. Caffo, S. E. Gentry, et al. "MELD exceptions and rates of waiting list outcomes." *American Journal of Transplantation*, 11(2011), 2362-2371.

⁵ Rodriguez-Luna, H., H. E. Vargas, A. Moss, et al. "Regional variations in peer reviewed liver allocation under the MELD system." *American Journal of Transplantation*, 5(2005), 2244-2247.

⁶ https://optn.transplant.hrsa.gov/media/1242/07_national_liver_review.pdf

⁷ <http://optn.transplant.hrsa.gov/governance/strategic-plan/>

What problem will this proposal solve?

A liver candidate receives a MELD⁸ or, if less than 12 years old, a PELD⁹ 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. Chaired by the Regional Representatives who are appointed to serve on the Liver and Intestinal Organ Transplantation Committee (hereafter, "the Committee"), these Regional Review Boards (RRBs) have different rules regarding representation, including program eligibility, length of service terms, and member rotation. 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 award practices, even among regions with similar organ availability and candidate demographics.^{10,11,12} This has led some to suggest that a national board replace the current RRB system.^{13,14} On average, 88.4% of initial, appeal, and extension requests submitted between July 1, 2014 and June 30, 2015 were approved; however, the regions approved as few as 75.8% and as many as 93.5% of requests during this timeframe. Excluding recipients transplanted in a status, the proportion of recipients transplanted with an exception score ranged from 29% to 61% among the regions.¹⁵

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. The RRB Chairs review over 1,000 standardized exception requests each year (including initial applications and extensions), which they approve because candidates meet criteria in policy.¹⁶ Chair review has been used as an alternative to programming these exceptions for auto-approval in UNetSM as is done for hepatocellular carcinoma (HCC) candidates that meet criteria. According to policy, some candidates meeting standardized criteria automatically receive exception extensions, as well. However, if the transplant program ever submits an exception request after the extension due date, the full review board must evaluate all subsequent extension requests despite meeting all other criteria in policy for approval. This has led to the RRBs reviewing an estimated 800 additional requests each year.

Additionally, there are problems associated with the way in which exception points are currently awarded. Currently, the MELD exception score for many standardized exception diagnoses begins at 22 points and automatically increases every three months to reflect a 10% increase in waitlist mortality, so long as the candidate continues to meet criteria in policy.¹⁷ This automatic three-month increase in standardized exception score is also referred to as the "MELD elevator."

The MELD elevator is problematic for several reasons. The waitlist mortality for non-exception candidates actually exceeds the mortality for exception candidates.¹⁸ Non-exception candidates are also transplanted

⁸ Model for End-Stage Liver Disease

⁹ Pediatric End-Stage Liver Disease

¹⁰ Argo, C. K., G. J. Stukenborg, T. M. Schmitt, et al. "Regional Variability in Symptom-Based MELD Exceptions: A Response to Organ Shortage?" *American Journal of Transplantation*, 11(2011), 2353-2361.

¹¹ Massie, A. B., B. Caffo, S. E. Gentry, et al. "MELD exceptions and rates of waiting list outcomes." *American Journal of Transplantation*, 11(2011), 2362-2371.

¹² Rodriguez-Luna, H., H. E. Vargas, A. Moss, et al. "Regional variations in peer reviewed liver allocation under the MELD system." *American Journal of Transplantation*, 5(2005), 2244-2247.

¹³ Gish, R. G., R. J. Wong, G. Honerkamp-Smith, et al. "UNOS Regional Variations in Appeal Denial Rates with Non-Standard MELD/PELD Exceptions: Support for a National Review Board." *Clinical transplantation* (2015).

¹⁴ Rodriguez-Luna, H., H. E. Vargas, A. Moss, et al. "Regional variations in peer reviewed liver allocation under the MELD system." *American journal of transplantation*, 5(2005), 2244-2247.

¹⁵ Based on OPTN data presented to the Committee on 10/20/2015

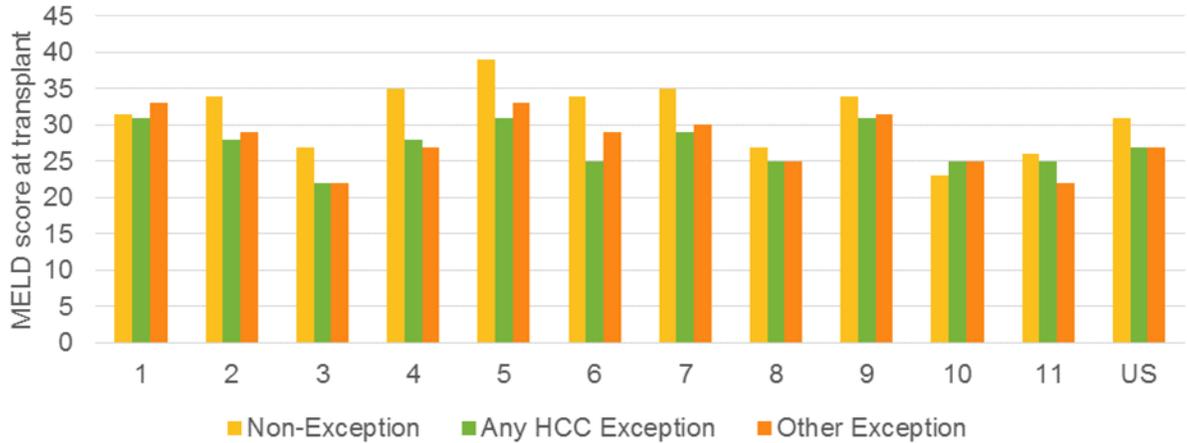
¹⁶ Policy 9.3.C: Specific MELD/PELD Exceptions, Organ Procurement and Transplantation Network Policies.

¹⁷ Policy 9.3.C: Specific MELD/PELD Exceptions, Organ Procurement and Transplantation Network Policies.

¹⁸ Massie, A. B., B. Caffo, S. E. Gentry, et al. "MELD exceptions and rates of waiting list outcomes." *American Journal of*

at higher MELD scores than those with approved exceptions (see **Figure 1**). Some have suggested that the MELD elevator has contributed to the escalation in MELD score at transplant that has occurred over the past decade (also known as MELD inflation).¹⁹

Figure 1. Adult deceased donor liver transplant recipients transplanted from July 1, 2014 – June 30, 2015, by OPTN region and MELD score at transplant



In November 2013, the OPTN/UNOS Board of Directors (hereafter, “the Board”) charged the Committee with developing a conceptual plan and timeline for the implementation of a national liver review board.

Why should you support this proposal?

The Committee proposes establishing a National Liver Review Board (NLRB) to provide fair, equitable, and prompt peer review of exceptional candidates. This proposal contains changes to OPTN/UNOS policy, including how to calculate and assign exception points, and updated operational guidelines (**Exhibit A**), which govern the review boards. The NLRB will be comprised of three specialty boards including Adult HCC, Adult Other Diagnosis, and Pediatrics. Assigning requests to the appropriate specialty board, rather than by geographic location, allows for reviewers with appropriate policy and clinical expertise to evaluate the request.

Every liver transplant program has the opportunity to be represented on the NLRB. An 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.²⁰ Representatives and alternates serve one-year terms, which may be renewed annually as long as the representative continues to fulfill obligations to the NLRB. Individuals may serve on more than one specialty board at the same time. All NLRB members must complete orientation prior to each term of service, which will include training on exception policy, operational guidelines, and guidance for evaluating common types of exceptions.

The NLRB will mitigate regional differences in award practices by establishing new voting procedures and guidance for assessing requests. Exception requests will be randomly assigned to five reviewers of the appropriate specialty board. A request must achieve four of five affirmative votes in order to be approved. If denied, the program has the opportunity to appeal to the same five reviewers.

Transplantation, 11(2011), 2362-2371.

¹⁹ Northup, P. G., N. M. Intagliata, N. L. Shah, et al. “Excess mortality on the liver transplant waiting list: Unintended policy consequences and model for End-Stage Liver Disease (MELD) inflation.” *Hepatology*, 61(2015), 285-291.

²⁰ Appendix F.7: Liver Transplant Programs that Register Candidates Less than 18 Years Old, Organ Procurement and Transplantation Network Policies (pending implementation)

If denied on appeal, the program may appeal to the Appeals Review Team (ART). The ART is comprised of nine NLRB members, and will meet via conference call on the same day and time each week, during which it will review any appeals that have been submitted over the course of the last week. The ART is a new addition to the NLRB proposal; it was not included in the January 2016 public comment proposal nor is it part of the current RRB structure.

Ultimately, the program may appeal to the Committee if the outcome of the ART appeal is not favorable. Notably, the Committee proposes eliminating the ability to override the decision of the NLRB. Since the override was implemented on February 4, 2016, only one transplant program has ever used it. The Committee believes its limited use, plus the ability to register a candidate as status 1A, negates the need for the override.

This proposal eliminates the regional agreements and instead tasks the Committee with developing or maintaining existing guidance to assess the most common types of exceptions. The Committee periodically reviews exception requests for opportunities to revise the MELD score or provide guidance for review board members. For example, the Board recently passed guidance to evaluate requests for candidates with neuroendocrine tumors, polycystic liver disease, primary sclerosing cholangitis, and portopulmonary hypertension.²¹ Unlike the Thoracic Organ Transplantation Committee, the Liver and Intestinal Organ Transplantation Committee must present review board guidance to the Board for approval.²² Consistent with thoracic policy, this proposal includes policy language that allows the Committee to provide specific recommendations to NLRB members without Board approval. In tandem with this proposal, the Committee also distributed for public comment three guidance documents to aid each of the specialty review boards in assessing exception requests.²³

The Committee also proposes improvements to the efficiency of the review board system to reduce the workload for reviewers and eliminate unnecessary delays in awarding exception points when appropriate. This proposal automates all standardized MELD/PELD exceptions in policy, an estimated 1,000 initial and extension requests each year. Proposed changes to standardized exception policy language are limited to those necessary to program UNetSM to automatically award exception points to those meeting criteria and are not intended to change the criteria for approval. This proposal also allows a candidate that meets standardized criteria to be eligible for automatic approval of a subsequent extension request after the liver transplant program misses a submission deadline, so long as the late request was reviewed by the NLRB. Currently the RRBs review an estimated 800 additional requests each year because of a missed extension deadline. With these improvements, the overall caseload will decrease by nearly 1,800 requests each year, which will be distributed equally among all reviewers nationally.

Finally, this proposal makes 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 for all adult liver recipients within the Donation Service Area (DSA). Creating a standard value, rather than allowing the review board to award points on a case-by-case basis, will ensure that similar diagnoses are treated similarly throughout the country, but also reflecting the pool of candidates with whom the requesting candidate is most likely to compete for organ offers by tying the score to the median MELD within the DSA.

²¹ Organ Procurement and Transplantation Network. *Guidance on MELD/PELD Exception Review*. Richmond, VA, 2015, available at <http://optn.transplant.hrsa.gov/resources/by-organ/liver-intestine/guidance-on-meld-peld-exception-review/>.

²² Compare Policy 10.2 [*Lung*] *Priority and Score Exceptions* with 9.3 [*Liver*] *Score and Status Exceptions*, Organ Procurement and Transplantation Network Policies.

²³ OPTN/UNOS Public Comment Proposal: "Liver Review Board Guidance Documents." Prepared by OPTN/UNOS Liver and Intestinal Transplantation Committee, January 23, 2017. Retrieved from: <https://optn.transplant.hrsa.gov/governance/public-comment/liver-review-board-guidance-201701/>

How was this proposal developed?

During the first round of public comment for the NLRB proposal, the Committee requested feedback from the community on the optimal method of assigning MELD score exception points, and whether it is desirable to eliminate the MELD elevator.²⁴ The Committee convened to review the feedback from public comment prior to proceeding with this iteration of the proposal.

Some commenters expressed concern that an NLRB would diminish the regions' abilities to respond to local or regional challenges unique to their region. The Committee agrees this may be a consequence of implementing an NLRB, but that this is an intended outcome. The NLRB is intended to standardize the award of exceptions and exception points nationwide to minimize the geographic disparity in exception practices. However, this proposal does not eliminate the potential for a region to pursue a policy variance if the region wishes to test a policy locally. The process for establishing and operating a variance is outlined in *Policy 1.3: Variances*.²⁵ Additionally, some commenters expressed concern that the NLRB may be overtaxed by the volume of exceptions. The Committee does not believe the volume of exceptions will rise, and therefore will not increase the NLRB's caseload any higher than current practice. The Committee also suggests there may be a decrease in the NLRB's workload, as programming will be implanted to automate repeat applications for HCC candidates whose cases fall off the standard automation track.

Many commenters expressed a general interest in understanding how exception points will be rewarded under the proposed NLRB structure, and reserved support or opposition until such details are available. Other feedback from public comment suggested exercising caution in moving toward this system, as it may disadvantage a candidate in a DSA that has a lower median MELD at transplant compared to a candidate with the same diagnosis in another DSA within the same region that has a higher median MELD at transplant. The Committee also considered this concern, but determined that candidates with these exception scores will not likely be competing for the same organ outside of their DSA due to the MELD thresholds for regional sharing that currently exist. Public comment generally supported removing the MELD elevator, acknowledging this device contributes to MELD inflation.

After considering the feedback from public comment, the Committee pursued modifications to the original public comment proposal. The Committee agreed on non-substantive changes, including reorganizing the proposed language to reflect the structure of current policies similar in concept, such as heart and lung policy on review boards, and reformatting the qualifying criteria for the standardized exceptions for each of the specific diagnoses and scores to appear as a list instead of a table. The Committee then discussed more substantive changes to the proposed policy, including various structural aspects of the NLRB and the way in which exception points should be rewarded for standardized adult and pediatric exception requests. Finally, the Committee considered how points should be awarded to candidates with non-standard exceptions.

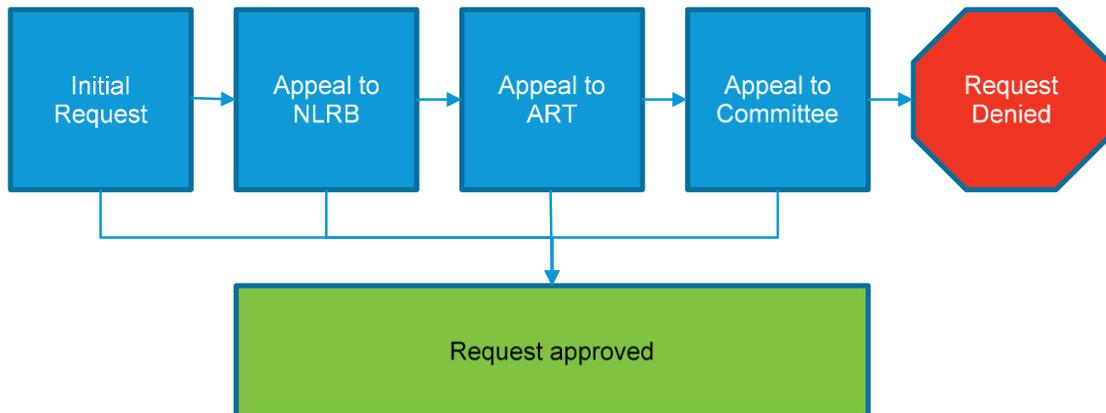
Structure of NLRB

Under this revised proposal, there are four potential phases of the lifespan of an exception or extension request: 1) initial request to the NLRB; 2) appeal to the NLRB; 3) appeal to Appeals Review Team (ART); and 4) appeal to the Committee.

²⁴ <https://optn.transplant.hrsa.gov/governance/public-comment/national-liver-review-board/>

²⁵ OPTN/UNOS Policy 1.3: Variances: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01

Figure 2: Lifespan of an Exception or Extension Request



In the original proposal, a case submitted to the NLRB would be assigned to five reviewers on the appropriate specialty board, but an appeal would be assigned to a different five reviewers. In the revised proposal, the Committee proposes that appeals will be submitted to the same five reviewers. This change allows reviewers to consider whether the program provided additional information that the reviewers previously requested. Logistically, the change also requires fewer members to review the request.

The Committee also proposes the establishment of the ART. At the beginning of each new service term, nine NLRB members are randomly assigned to serve each month of the year on the ART. There may be multiple ARTs, depending on the volume of cases, or perhaps an ART to serve each time zone in the continental United States. The ART will meet via conference call at the same day and time each week, to alleviate the difficulty of scheduling ad hoc conference calls to review appeals, as the previous policy proposal permitted. If the case is appealed to the Appeals Review Team, there will be two chances for the transplant program to join a conference call. If the ART does not reach quorum after two chances (at least five of the nine members of the ART), then the requested points will be awarded. If the program cannot make the call, it can provide the ART with written materials instead of holding a conference call. There will be no chair of the ART – UNOS staff will organize and facilitate the calls. UNOS staff will also communicate the outcome of the ART’s review to the transplant program. The Committee will monitor the number of ART calls to determine if ART calls are necessary in the future.

The final structural change the Committee proposes is the elimination of the ability to override the NLRB’s decision. Since February 2016, programming in WaitlistSM permits a transplant program to “override” the decision of the review board to permit the candidate to be registered at the requested score if the transplant program does not agree with the review board’s decision. If a transplant program uses the override button, the Committee reviews the case to determine whether the use was justified. If the Committee does not believe the use was justified, it may refer the case to the Membership and Professional Standards Committee.

Ultimately, the Committee agreed that the override button should be removed. It is rarely used and is a source of confusion. Only one transplant program has intentionally used the override button since its implementation. Additionally, if a candidate is very urgent and the transplant program does not believe there is enough time to navigate the exception request and appeal process, the transplant program can register the candidate as status 1A. Such a listing would also be reviewed by the Committee, and achieves the same end as the override button. Therefore, the Committee proposes removing the override button to remove some complexity from the exception appeals process and programming.

Standardized MELD Exception Points for Adult Candidates

The current “elevator” policy for candidates with standardized exceptions permits exception points values to gradually increase at certain time intervals. The Committee agreed that the current exception points policy is problematic in two ways: 1) it is not uniformly applied, so candidates in different regions receive different points values for similar conditions, leading to inequity in access to transplant; and 2) the MELD elevator contributes to MELD inflation, which in turn increases the waitlist mortality for non-exception candidates and drives non-exception candidates to be transplanted at higher MELD scores.

The Committee discussed whether the concept of changing policy to assign exception points based on a “fixed floor” (certain value below MMaT in the DSA) is preferable to the current system. The Committee theorized that applying the fixed floor to all exception candidates would help solve both of these problems: it would standardize the assignment of exception points for the same diagnoses across the country and would reduce inflation of exception scores.

The Committee therefore requested the SRTR perform a policy simulation analysis using the Liver Simulation Allocation Model (LSAM) tool to analyze the impact of fixing the score at a certain value below the median MELD at transplant in the DSA.²⁶ The Committee requested assessment of multiple policy scenarios awarding either MMaT minus 1, minus 2, minus 3, or minus 5 MELD points to exception candidates. The results indicated that the percentage of transplants for candidates with exceptions would decrease while the percentage of transplants for candidates without exceptions would increase under scenarios that awarded fewer points to exception candidates, but there would otherwise be no major shift in waitlist mortality or transplant rates, particularly under the MMaT minus three scenarios. The Committee discussed whether exception candidates would have to wait longer to receive a transplant than they do under the current scheme, and does not anticipate this as an outcome. In fact, the Committee believes exception candidates may be transplanted more quickly under the new scheme. Under the current policy, the exception candidates must wait until their points escalate enough to enable them to compete for offers. Under the new scheme, the candidates will receive the appropriate value immediately, and therefore may not end up waiting as long for a transplant. Additionally, the Committee acknowledges that the fixed floor will result in more patients waiting at the same score, which would result in candidates with longer wait time at that score receiving offers before those with less wait time at the score. The Committee was concerned that this means the system is defaulting to wait time. However, the current policy also relies heavily on wait time at a certain score; candidates simply move more quickly out of the score due to the elevator. Therefore, the Committee does not believe this change will cause an unintended consequence and will retain the status quo.

The Committee debated between assigning standardized exception points equal to MMaT minus three or minus five. The Committee noted that MMaT minus three is close to status quo, as candidates with exceptions now are generally transplanted with a score about three points below the MMaT, with the exception of two regions.²⁷ The Committee was concerned that MMaT minus five would result in too significant of a change, which was not palatable given the other aspects of the exception process that are also proposed to change. However, some noticed that for certain regions, under MMaT minus three the number of transplants for candidates with HCC exceptions would not decrease, and may even increase. Nevertheless, the Committee determined that most of the regions would experience the intended effect even under MMaT minus three, and therefore opted for MMaT minus three. The Committee’s intent is to use the MMaT minus three assignment for candidates with standardized exception points as a starting policy, and to review and update the policy going forward as needed in case this change results in unintended consequences.

After reviewing this information, the Committee determined that, for adult candidates, assigning exception scores equal to three points below the median MELD at transplant in the DSA where the candidate is

²⁶ SRTR Analysis Report, “Data Request from the OPTN Liver and Intestinal Organ transplantation Committee.” Presented October 17, 2016. LSAM - LI2015_03 DR1.

²⁷ SRTR Analysis Report, “Data Request from the OPTN Liver and Intestinal Organ Transplantation committee.” Presented December 14, 2016. LSAM LI2016_03.

registered was the best option. This option achieves the goal of standardizing the award of exception points for the same diagnoses across the country while tying them to the local allocation unit, and also is an incremental change that introduces the concept of the fixed floor while removing the elevator. The Committee does not anticipate that this will have a major impact on access to transplant for candidates with exceptions, but will achieve more uniformity and introduce a new schema for assigning exception points to candidates. The Committee will closely monitor the effects of this policy and will adjust if necessary.

Next, the Committee considered whether, for adult candidates, the fixed floor should apply to all diagnoses, some diagnoses, or only to HCC exception candidates. The Committee agreed that, when clinically appropriate, the same fixed floor should apply across all diagnoses to give all exception candidates within the DSA the same exception points value. However, the Committee agreed that there are two diagnoses that should be excluded from the MMaT minus three schema due to their disparate waitlist mortality risks: hepatic artery thrombosis (HAT) and primary hyperoxaluria. The Committee believes candidates that meet the criteria for a standardized exception for HAT should continue to receive an exception MELD score of 40, given the severity of the disease and the need for an immediate transplant. The Committee also believes that candidates with primary hyperoxaluria, or oxalosis, are also more urgent than most other exception candidates. These candidates are usually on dialysis, need a liver and a kidney, and are not candidates for living donation, so the candidate needs the additional points to gain access to a quality liver and kidney combination. Therefore, the Committee proposes assigning these candidates a score equal to the MMaT in their DSA.

The Committee considered whether candidates that meet the criteria for a standardized HCC exception, accounting for about 80% of standard exceptions, should have the same point assignment as the other exceptions.²⁸ The LSAM analysis showed that the transplant rate was slightly higher but similar for HCC candidates compared to other exception candidates if the exceptions were assigned points a certain level below median MELD at transplant. Ultimately, the Committee agreed that HCC candidates should be treated similarly to other standardized exception candidates, but that the current “delay” policy should remain in place to temper the effect of this score assignment. The delay policy requires candidates meeting the criteria for a standardized HCC exception to wait six months registered at their lab MELD score before the candidate can receive the effect of the exception score. The intent of the delay policy is to alleviate the risk of transplanting candidates with biologically aggressive tumors too quickly. The Committee agreed this policy is very important and should remain in place.

The Committee also discussed whether to retain the “cap” aspect of the current HCC exception score policy. The cap mitigates the elevator by ensuring that, no matter how long an HCC candidate waits with an approved exception, their score cannot exceed a MELD score of 34. The Committee agreed that the cap of 34 should remain in place for HCC candidates, and ultimately agreed it should be extended to all adult candidates with approved standardized exceptions. This follows a practice that is already adopted in Region 4 that caps non-standardized exceptions at a MELD score of 34. This would help achieve greater nationwide uniformity, by preventing candidates in regions with particularly high MMaTs from receiving an undue advantage under the new policy. It also provides greater access for candidates that are registered according to their lab MELD instead of an exception. Additionally, the cap will help the transition to future broader sharing policies, by eliminating the concern that certain regions benefit from a higher MMaT and therefore their patients will always have better access under broader sharing than regions with lower MMaTs. Some members expressed concern that the cap may disadvantage non-HCC exception candidates in certain regions, but ultimately the Committee determined there are very few non-HCC exception candidates so this policy change will not have a major impact on them. Additionally, a transplant program can always request the NLRB grant a different MELD score to an exception candidate if the candidate is more urgent than others awaiting with the same diagnosis. Therefore, if the exception points calculation based on the MMaT of the DSA would result in a candidate receiving a MELD score higher than 34, the candidate will only receive a MELD score of 34.

²⁸ OPTN/UNOS Data: MELD/PELD Exception Cases Submitted to the RRBs Between 01/01/2016-12/31/2016. Analysis based on OPTN data as of December 31, 2016.

Standardized MELD and PELD Exception Points for Pediatric Candidates

After determining the value of the fixed score for adult standardized exception candidates, the Committee considered how to assign standardized exception points to pediatric candidates. The Committee sought input from the Pediatric Liver Work Group, comprised of members of the OPTN/UNOS Pediatric Transplantation Committee, the Liver Committee, and other pediatric liver transplant experts, regarding whether and how the fixed points concept should apply to pediatric candidates less than 18 years old seeking a standardized exception.

The Work Group first debated whether the exception points system for pediatric candidates should be changed at all. At first, the Work Group agreed the standardized points system that currently exists for pediatric candidates should not be changed because there may not be enough data to support such a change and the Work Group did not want to disadvantage pediatric candidates inadvertently, and the MELD/PELD system for pediatric candidates is under consideration for modification due to concerns that it does not adequately prioritize pediatric candidates. Additionally, LSAM analysis revealed that if pediatric patients were to be assigned any points value below median MELD at transplant, their transplant rates may decrease.²⁹ However, the Work Group quickly realized that retaining status quo for the pediatric points assignment would indeed disadvantage pediatric candidates with standardized MELD/PELD exceptions in the new proposed system for adult points assignments, because the pediatric scores set by existing policy would almost always be less than the median MELD at transplant in the DSA.

The Work Group therefore agreed to change the points assignment system for pediatric candidates. For most diagnoses, the Work Group agreed that candidates meeting the criteria for the standardized exceptions should receive a score equal to the median MELD at transplant. These pediatric candidates would receive a slight advantage over adult candidates that qualify for the same diagnosis. The Work Group agreed this advantage in access to transplant for pediatric candidates is appropriate, given the medical implications of delayed access to transplantation on growth and development. Providing preference to pediatric candidates is also supported by the Prudential Lifespan Account and Fair Innings Concept documented in OPTN's "Ethical Principles of Pediatric Organ Allocation."³⁰

The cohort for this calculation is slightly different than the adults; for adults, the cohort includes all adult liver transplant recipients over the last year. For pediatric candidates, the Committee proposes different cohorts for candidates between 12 to 17 years old and for candidates less than 12 years old. For candidates between 12 to 17 years old, the Committee proposes that the cohort includes all liver recipients over the last year. The Committee determined it is important that the cohort used for this age group includes pediatric candidates because it applies to them, but cannot be limited to pediatric candidates because the cohort would be too small and variable. The Committee determined that the calculation for pediatric candidates less than 12 should be based on the median MELD at transplant for all liver recipients in the region instead of the DSA. This is because candidates less than 12 years old compete for organs from pediatric donors in their region, rather than just in their DSA. It is therefore fair to make their scores standard across the region.

Three diagnoses are excluded from assigning median MELD at transplant for pediatric standardized exceptions. First, the Committee proposes that candidates meeting the criteria for the standardized exception for HAT should continue to receive a score of 40. Adult and pediatric HAT candidates currently receive a MELD or PELD score of 40 if they qualify for the standardized exception, and the Committee believes this higher score continues to be warranted for this group due to their higher waitlist mortality risks. Second, pediatric candidates that qualify for the standardized exception for primary hyperoxaluria should receive a score equal to three points above the MMaT in the DSA (or the region, if the candidate is

²⁹ SRTR Analysis Report, "Data request from the OPTN Liver and Intestinal Organ Transplantation Committee." Presented October 17, 2016. LSAM – LI2015_03_DRI

³⁰ OPTN White Paper: *Ethical Principles of Pediatric Organ Allocation*, updated November 2014. <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/>

less than 12 years old), to ensure these pediatric candidates receive proper advantage over adult candidates with primary hyperoxaluria.

Finally, to make the assignment of points for pediatric candidates with hepatocellular carcinoma (HCC) less complicated, the Work Group and Committee agreed that all HCC candidates less than 18 years old should receive a MELD or PELD score of 40. In effect, these candidates will be treated the same as pediatric candidates that qualify for the HAT standardized exception, which the Committee agreed to based on similar medical urgencies. Assigning pediatric HCC candidates a fixed score also eliminates the three-month elevator that exists in current policy, but permits the transplant program to request additional exception points for their HCC candidates if necessary.

The Committee determined that the cap of a MELD score of 34 that is proposed to be applied to the adult candidates with standardized exceptions should not be applied to pediatric candidates less than 18 years old. Currently there is no cap for pediatric candidates, and the Committee did not think there was a reason to implement one.

Non-Standardized MELD and PELD Exception Points

The Committee also considered how to assign points to candidates that do not meet the criteria for the standardized exceptions. The Committee recommends that the NLRB members assign non-standardized exception points similarly to standardized exception requests. Therefore, the Committee recommends that the NLRB award adult candidates exception scores equal to three points below the median MELD at transplant in the DSA, and pediatric exception scores equal to the median MELD at transplant in the DSA. The NLRB can use its discretion to assign more or less points depending on the candidate's medical urgency. This recommendation is included in the guidance document proposal.³¹

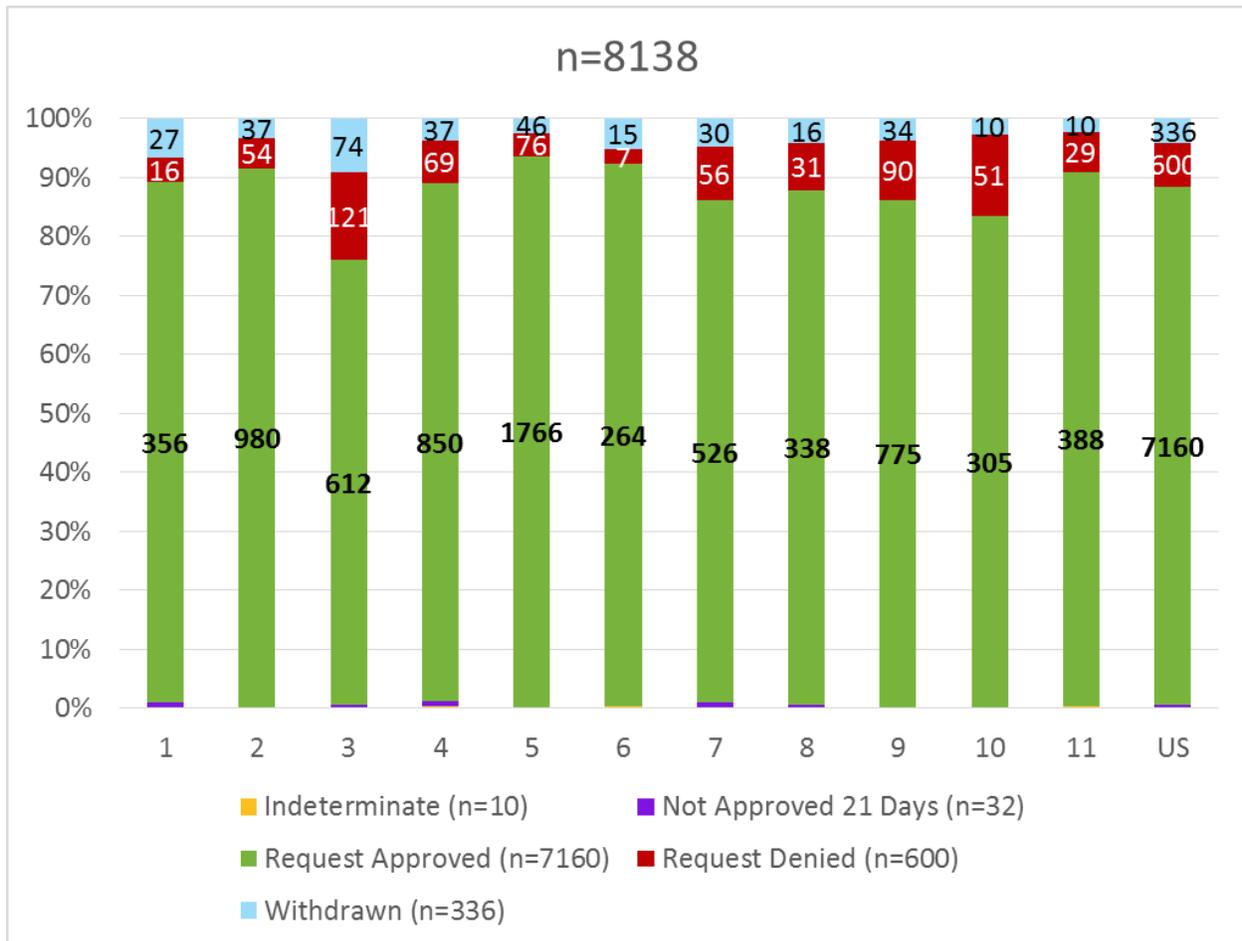
How well does this proposal address the problem statement?

Structure of NLRB

As discussed above, regional differences in MELD/PELD score exception submission and approval rates have been well documented in the literature. These have been confirmed by recent OPTN data provided to the Committee (**Figure 3**).

³¹ OPTN/UNOS Public Comment Proposal: "Liver Review Board Guidance Documents." Prepared by OPTN/UNOS Liver and Intestinal Transplantation Committee, January 23, 2017. Retrieved from: <https://optn.transplant.hrsa.gov/governance/public-comment/liver-review-board-guidance-201701/>

Figure 3: RRB Decisions (All Cases)



The Committee believes that a national structure for exceptional case review will lead to more equitable review outcomes. It will achieve this by:

- Creating specialty boards that allow for reviewers with appropriate policy and clinical expertise to evaluate the request.
- Giving every liver transplant program the opportunity to be represented on the NLRB.
- Requiring orientation and education for all reviewers at the beginning of each term of service, which will include training on exception policy, operational guidelines, and guidance for evaluating common types of exceptions.
- Instituting new voting procedures that assign requests randomly to reviewers and require a super majority vote.

This proposal also improves the efficiency of the exception process. The RRB Chairs review over 1,000 standardized exception requests each year (including initial requests and extensions), which they approve since the requests meet criteria in policy. Their review of these cases is an inappropriate use of the peer review system, since their medical judgment is not critical to evaluate these cases. Automatically awarding exception points to candidates meeting criteria in policy will reduce the workload for reviewers and eliminate unnecessary delays in awarding exception points. Based on OPTN data, the Committee estimates that automating the standardized exceptions will reduce the overall workload of the NLRB by nearly 1,800 requests each year.

Standardized Exception Scores

The Committee first analyzed the median MELD/PELD at transplant for deceased donor liver transplants in 2015, overall, and stratified by region, DSA, age, and exception status.³² **Figure 4** displays the median MELD/PELD at transplant by region for 2015.

Figure 4: Median MELD/PELD at Transplant by Region for 2015

Region	N	Median MELD/PELD
1	230	31
2	754	30
3	1230	25
4	636	29
5	903	35
6	194	28.5
7	502	30
8	436	25
9	271	33
10	577	23
11	664	25
US	6397	28

The Committee noted interest in adopting a standard approach for awarding exception points. It considered using an exception point system that would award points at a certain level under the median MELD at transplant (MMaT) in the DSA, standardizing the approach to exception points assignments while still being sensitive to differences between DSAs. It therefore requested that the SRTR simulate alternative exception point scoring scenarios that award exception points at a certain level below the (MMaT) in the DSA, including:

- 1 point below MMaT of all recipients in the DSA where the candidate is listed (MMaT – 1)
- 2 points below MMaT of all recipients in the DSA where the candidate is listed (MMaT – 2)
- 3 points below MMaT of all recipients in the DSA where the candidate is listed (MMaT – 3)
- 4 points below MMaT of all recipients in the DSA where the candidate is listed (MMaT – 4)
- 5 points below MMaT of all recipients in the DSA where the candidate is listed (MMaT – 5)

The SRTR simulation of the above policy scenarios were assessed and compared to simulation of current liver allocation policy, including Share 35 but not including HCC cap and delay and MELD-Na.³³ The study population included transplant candidates listed on liver waiting lists as of December 31, 2006, and candidates added to those waiting lists between January 1, 2007, and December 21, 2011. This includes organs donated between January 1, 2007, and December 21, 2011. The Committee requested the analysis address two research questions:

1. What are the proportions of exception patients who undergo transplant compared with non-exception patients who undergo transplant in these scenarios?

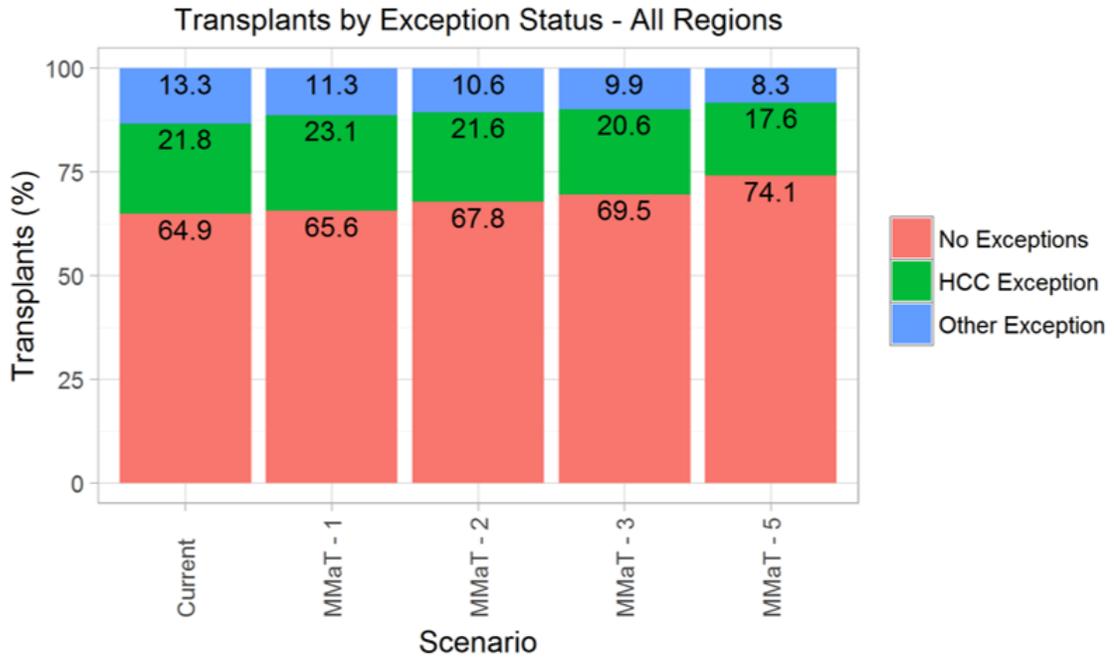
³² OPTN Data Request: Median MELD/PELD at Transplant for Deceased Donor Liver Transplants Performed in the Calendar Year 2015. Analysis based on OPTN data as of July 15, 2016.

³³ SRTR Analysis Report, "Data request from the OPTN Liver and Intestinal Organ Transplantation Committee." Presented October 17, 2016. LSAM – LI2015_03_DRI

2. What is the waitlist mortality and post-transplant mortality for exception and non-exception patients in these scenarios?

The analysis showed that the proportion of candidates with no exceptions undergoing transplant is estimated to increase as the awarded exception points in a scenario decrease. See **Figure 5**.

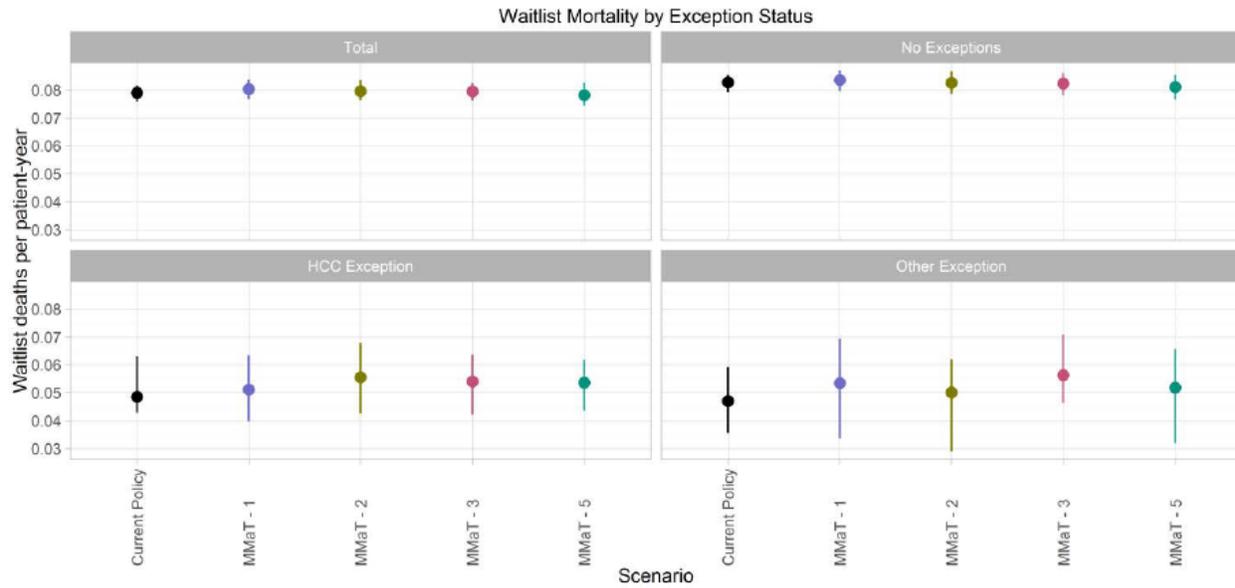
Figure 5: Proportion of transplants by exception status



This was a key research question asked by the Committee, and an intended outcome of the proposed policy change.

Waitlist mortality may increase slightly or remain the same for all candidates in the MMaT – 1 scenario, and waitlist mortality may decrease slightly or remain the same for all candidates in the MMaT – 5 scenario. See **Figure 6**.

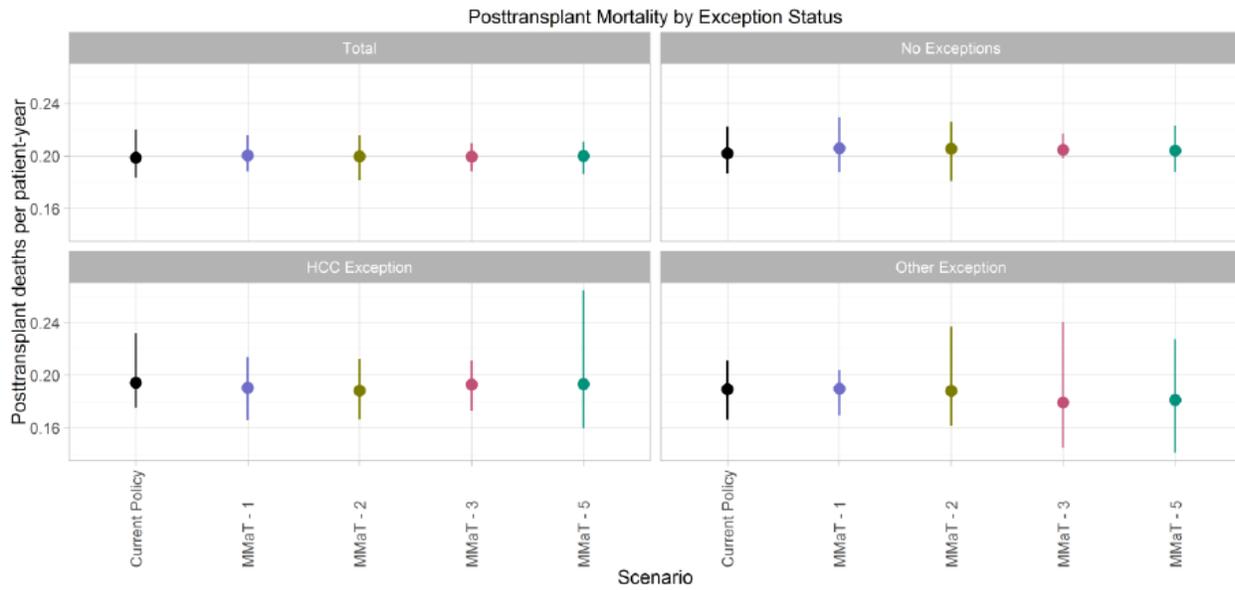
Figure 6: Waitlist mortality rates by exception status



However, minimum to maximum estimates across the simulated iterations of each scenario overlap with the current scenario, indicating that it is not definite that this change will occur. Waitlist mortality rates for exception candidates may increase slightly or remain the same for HCC exception and other exception candidates compared with current policy, but minimum-maximum ranges of estimates overlap. Under current and alternative policy scenarios, waitlist mortality for exception candidates is lower than for candidates with no exceptions. The Committee noted that this proposed policy is not intended to impact waitlist mortality, and the Committee is satisfied that the MMaT minus three scenario is not expected to significantly increase waitlist mortality.

Post-transplant mortality is not projected to change, and rates are similar for recipients with no exception, HCC, and other exceptions. **Figure 7.**

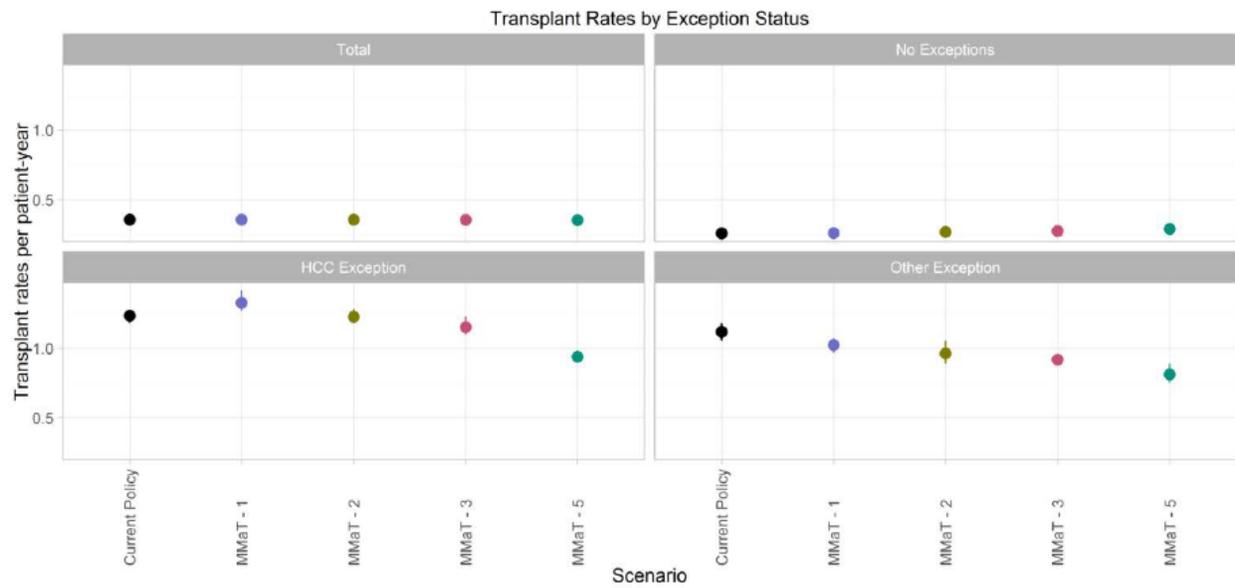
Figure 7: Post-transplant mortality rates by exception status



Again, the Committee noted that this proposal is not intended to impact post-transplant mortality, and is satisfied that MMaT minus three scenario is not expected to significantly affect post-transplant mortality.

Transplant rates may decrease slightly for all patients as the number of points assigned below MMaT increases. **Figure 8.**

Figure 8: Transplant rates by exception status



This is driven by the decrease in transplant rates for candidates with HCC and other exceptions. The overall transplant rate for exception candidates is higher than for non-exception candidates. The Committee intends for these shifts to occur.

The Committee requested that the SRTR provide this analysis stratified by region.³⁴ The analysis showed similar patterns to the nationwide assessment in transplant rates, waitlist mortality, and post-transplant mortality by exception status for the MMaT minus three scenario. In all regions, the proportion of non-exception candidates undergoing transplant is estimated to increase slightly as assigned exception points by MMaT decrease. **Figure 5.**

The greatest increase for non-exception candidates receiving transplants is under the MMaT-5 scenario. In certain regions with a higher current MMaT (4, 5, 7, and 9), the proportion of non-exception candidates undergoing transplant decreases in the MMaT-1 scenario. Although the proportion of HCC exception candidates undergoing transplant decreases as the points below MMaT increase, the proportional change from the current scenario to MMaT-3 scenario is relatively small. By contrast, the proportion of HCC exception candidates undergoing transplants in the MMaT-5 scenario drops more sharply compared to both the current and the other MMaT- scenarios. It is because of the relatively small impact of the MMaT-3 scenario as compared with MMaT that the Committee proposes applying MMaT-3 to most standardized diagnoses.

After reviewing the modeling data, the Committee felt confident that the proposed MMaT-3 scheme will achieve the goal of providing equity in access to transplant for liver candidates by standardizing the award of exception points, without significantly impacting transplant rates, waitlist mortality, or post-transplant mortality.

Which populations are impacted by this proposal?

This proposal promotes equitable access to transplant for liver candidates whose calculated MELD or PELD score does not accurately reflect the severity of their disease. This includes pediatric candidates, who have a disproportionately high rate of transplant under exception.³⁵ This proposal also benefits approximately 500 candidates each year who meet the criteria for standardized MELD exceptions in policy by automatically approving their exception score upon submission of their requests, and by standardizing the way in which exception points are granted.

In addition, these changes will improve access to transplant for adult candidates without exception points, who are transplanted at higher MELD scores than those with approved exceptions (see **Figure 1**).

This proposal also affects current RRB members and prospective NLRB members (see “How will members implement this proposal?”).

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* The primary goal for this proposal is to improve equity in access to transplant by establishing a national structure for exceptional case review in which all liver transplant programs have an equal opportunity for representation. The NLRB seeks to mitigate regional differences in award practices by establishing new voting procedures and giving the Committee the ability to develop national guidance for assessing common requests. Removing the exception points elevator and assigning points based on the median MELD in the candidate’s DSA also standardizes the award of exception points nationally and may lead to

³⁴ SRTR Analysis Report, “Data Request from the OPTN Liver and Intestinal Organ Transplantation committee.” Presented December 14, 2016. LSAM LI2016_03.

³⁵ From July 1, 2014-June 30, 2015, 32% of all deceased donor liver transplants in 0-11 year old recipients were performed under a PELD exception.

overall MELD “deflation.” This ensures that candidates with similar medical urgency for transplant have similar access based on their similar MELD scores, regardless of where they are geographically located.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The NLRB promotes fair and equitable assignment of exception points to appropriate candidates, which contributes to better waitlist outcomes for both exceptional candidates and those who will be transplanted on the basis of the calculated MELD/PELD score.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This proposal improves the efficiency of the review board system by reducing the workload for reviewers by approximately 2,000 requests each year and eliminating unnecessary delays in awarding exception points when appropriate.

How will the OPTN implement this proposal?

This proposal will require programming in UNetSM, estimated at an enterprise level. However, this programming will eliminate several manual processes for UNOS Review Board staff, which will result in long-term cost-savings. Review Board staff will still be responsible for facilitating conference calls for programs that choose to appeal a case to the NLRB after a second randomized review results in a denial.

On the date of implementation, liver candidates with approved standardized MELD or PELD exception scores will either retain their existing exception scores, or will be assigned the new score according to the proposed policy, whichever value is higher. The Committee does not want to take points away from candidates who were previously approved at a higher value, but also does not want to disadvantage candidates with existing scores if their existing scores are lower than other similarly situated candidates under the newly designed exception score system.

Every six months, when the system re-calculates the six month cohort, the following will occur for candidates that are registered under a standardized exception that uses the MMaT fixed floor scheme:

- If the MMaT increases, then candidates currently waiting with the previous MELD exception score will experience an increase in exception score in real time
- If the MMaT decreases, candidates with existing MELD exceptions will retain their exception score until they are due for an extension

The OPTN will work with the Committee to develop the orientation training all NLRB representatives and alternates must complete before beginning their term of service. This proposal also requires an instructional program for members to educate them on changes to policy and how it will affect their work, especially the submission of exception requests. The proposal will be monitored for specific educational needs throughout the public comment and approval process. Communication and education efforts will provide members with resources to prepare for implementation and compliance.

Specific communication and educational efforts associated with this proposal may include:

- Policy notice outlining policy changes
- System notice outlining UNetSM system changes and updates to Help Documentation
- UNetSM system training with system changes
- Articles on the OPTN and Transplant Pro websites
- Presentations at regional meetings

How will members implement this proposal?

This proposal will primarily impact transplant hospitals. There is no anticipated effect on OPOs or histocompatibility laboratories. Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community.

Transplant Hospitals

Participation on the NLRB

Similar to the current review board system, which provides every active liver transplant program the opportunity to be represented on the regional review board, for the proposed NLRB 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.³⁶ 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 (**Exhibit A**). 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, extension requests, and appeals. The representative must notify UNOS in UNetSM of an absence, during which the alternate will fulfill the responsibilities of the representative.

If after 7 days the representative has not voted on an open request, then it will be randomly reassigned to another representative. If a representative or alternate does not vote on an open request within 7 days on three separate instances within a 12-month period, the Chair will remove the individual from the NLRB. A representative or alternate who has been removed for failure to perform the duties required is not eligible to serve again for 3 years.

A liver program may appeal a denied request to the NLRB. All reviewer comments are available in UNetSM. The NLRB advises programs to respond to the comments of dissenting reviewers in the appeal. The appeal is assigned to the same five members of the appropriate specialty board. The appeal must achieve four out of five affirmative votes in order to be approved. If the appeal does not achieve the necessary four affirmative votes, it is denied.

If the appeal is denied, the liver program may request a conference call with the Appeals Review Team (ART). The ART is comprised of nine NLRB members, who, at the beginning of each service term, are randomly assigned to serve one month of the year on the ART. Members can indicate specific months during which they would be unavailable to serve on the ART. An NLRB member will be selected to serve for no more than one month each year on the ART. The ART meets via conference call at the same day and time each week.

If the ART denies the request, the liver program may initiate a final appeal to the Liver and Intestinal Organ Transplantation Committee. Referral of cases to the Liver and Intestinal Organ Transplantation Committee will include information about the number of previous referrals from that program and the outcome of those referrals. The transplant program no longer has the ability to override the decisions of the NLRB or ART: it must follow the sequence outlined above for appeals.

³⁶ Appendix F.7: Liver Transplant Programs that Register Candidates Less than 18 Years Old, Organ Procurement and Transplantation Network Policies (pending implementation)

Submission of Exception Requests

This proposal does not change the qualifying criteria for standardized exception requests, and does not fundamentally change the way in which exception requests are submitted to the review board. However, as described in the “Will this proposal require members to submit additional data?” section below, the exception requests forms will be modified to include discrete data fields to help automate the standardized exception request process.

Will this proposal require members to submit additional data?

No, the proposal does not require additional data collection. However, in order to automate approval of the standardized exceptions, liver programs will have to submit required information in discrete data fields in UNetSM instead of in narrative form as they do currently. The principles of data collection used to support this change are:

1. Develop transplant, donation and allocation policies: The Committee will periodically review the data to determine if revisions to the standardized exception criteria or to the MELD score calculation are needed.
2. Determine if Institutional Members are complying with policy: The OPTN requires that this data is submitted to demonstrate that the candidate meets criteria for automatic assignment of additional MELD or PELD points.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine monitoring of OPTN members. Any data submitted to the OPTN Contractor may be subject to OPTN review, and members are required to provide documentation as requested.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

To assess the efficacy of the NLRB, the UNOS Research Department will analyze a number of relevant outputs in a pre vs. post analysis. Such analyses will be performed at 6-month intervals up to 36 months post-implementation (or longer if requested by the Committee). Both national results and results by region of the program requesting the exception (where feasible) will be compared. Some analyses will also be performed by specialty board type (i.e., Adult HCC, Adult Other Diagnosis, and Pediatric). Note that many exception requests for diagnoses that currently require review by the RRB chair will be automated under the NLRB system. For this reason, some of the post-implementation results will not be directly comparable to those from the pre-implementation era.

Relevant analyses:

- Total number of exception cases automatically approved and those reviewed by the NLRB, overall and by diagnosis (note: exceptions with “Other Specify” diagnoses will be reclassified into diagnostic categories as feasible)
- Number and percent Approved/Denied/Appealed, overall and by diagnosis
- Number and percent of cases that required NLRB review that were returned to the auto-approval track
- Number of cases not closed within time required by policy
- Distribution of MELD/PELD scores approved/denied by the NLRB, by initial/extension/appeal and diagnosis
- Distribution of time to close cases

- Distribution of annual number of cases reviewed per NLRB member
- Waiting list drop-out rates (death or too sick) for candidates with initial exceptions versus those without exceptions and, if possible, the drop-out rates for candidates who were denied exception points
- Number and percentage of deceased donor transplants by exception status (yes/no) and type (e.g., HCC, other standard exception, other specify)
- Distribution of MELD and PELD scores at transplant (mean, median, and standard deviation) for each DSA and Region, by MELD/PELD exception status (yes/no) and type (e.g., HCC, other standard exception, other specify), compared to data prior to implementation and to every prior 6-month evaluation period

Policy or Bylaws 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~~ 1. Include a request for a specific MELD or PELD score-
- ~~2. Justify why accepted~~ 2. 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.~~

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

48 The NLRB must review exception or extension requests within 21 days of the date the request is
49 submitted to the OPTN Contractor. If the NLRB fails to make a decision on the initial exception or
50 extension request by the end of the 21 day review period, the candidate will be assigned the
51 requested MELD or PELD exception score.

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9.4.B.i: NLRB Appeals

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

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

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

63 If the NLRB denies the appeal for an exception or extension request, the candidate's
64 transplant program may further appeal to the Appeals Review Team (ART) within 7
65 days of receiving notification of the denial. If the transplant program appeals the
66 exception or extension request to the ART, the ART must review the request within
67 14 days of the date the appeal is submitted to the OPTN Contractor. If the ART fails
68 to make a decision on the appealed request by the end of the 14 day ART appeal
69 review period, the candidate will be assigned the requested MELD or PELD
70 exception score.

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9.4.B.iii Committee Appeals

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

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9.34.C Specific Standardized MELD/ or PELD Score Exceptions

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

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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 Polynuropathy (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.
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in <i>Policy 9.1.A: Adult Status 1A Requirements</i>	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	The information required according to <i>Policy 9.3.F: Candidates with Hepatocellular Carcinoma (HCC).</i>	See <i>Policy 9.3.F: Candidates with Hepatocellular Carcinoma (HCC).</i>
Hepatopulmonary Syndrome (HPS)	All of the following: 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 9.3.D — Pediatric Liver Candidates with Metabolic Diseases.</i>	See <i>Policy 9.3.D — Pediatric Liver Candidates with Metabolic Diseases.</i>

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

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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 9.4.C.i: Requirements for Cholangiocarcinoma MELD or PELD Score Exceptions
- Cystic fibrosis, according to Policy 9.4.C.ii: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions
- Familial amyloid polyneuropathy, according to Policy 9.4.C.iii: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions
- Hepatic artery thrombosis, according to Policy 9.4.C.iv: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions
- Hepatopulmonary syndrome, according to Policy 9.4.C.v: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions
- Metabolic disease, according to Policy 9.4.C.vi: Requirements for Metabolic Disease MELD or PELD Score Exceptions

- Portopulmonary hypertension, according to Policy 9.4.C.vii: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions
- Primary hyperoxaluria, according to Policy 9.4.C.viii: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions
- Hepatocellular carcinoma, according to Policy 9.4.C.ix: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception

9.4.C.i 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:
 - a. Biopsy or cytology results demonstrating malignancy
 - b. Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
 - c. AneuploidyThe 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 allocation 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.

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

161
162
163 The OPTN Contractor will re-calculate the median allocation MELD at transplant
164 every 180 days using the previous 365-day cohort. If there have been fewer than 10
165 transplants in the DSA in the previous 365 days, the median MELD at transplant will
166 be calculated for the region where the candidate is registered. At each 180 day
167 update, if the median MELD increases, candidates with existing standardized score
168 exceptions will be assigned the increased score to match the re-calculated median
169 MELD. However, if the median MELD decreases at the 180 day update, candidates
170 with existing standardized score exceptions will not be assigned a score to match the
171 re-calculated median until the candidate is due for an extension.

172
173 In order to be approved for an extension of this MELD or PELD score exception,
174 transplant hospitals must submit an exception extension request according to *Policy*
175 9.4.D: MELD or PELD Score Exception Extensions, and provide cross-sectional
176 imaging studies of the chest and abdomen that exclude intrahepatic and extrahepatic
177 metastases. These required imaging studies must have been completed within 30
178 days prior to the submission of the extension request.

179
180 **9.4.C.ii Requirements for Cystic Fibrosis MELD or PELD Score**
181 **Exceptions**

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

186
187 A liver candidate at least 18 years old at the time of registration that meets the
188 requirements for a standardized MELD score exception will be assigned a score that
189 is 3 points below the median allocation MELD at transplant for liver recipients at least
190 18 years old in the DSA where the candidate is registered. If the candidate's
191 exception score would be higher than 34 based on this calculation, the candidate's
192 score will be capped at 34.

193
194 A liver candidate 12 to 17 years old at the time of registration that meets the
195 requirements for a standardized MELD score exception will be assigned a score
196 equal to the median MELD at transplant for all liver recipients in the DSA where the
197 candidate is registered.

198
199 A liver candidate less than 12 years old at the time of registration that meets the
200 requirements for a standardized PELD score exception will be assigned a score
201 equal to the median MELD at transplant for all liver recipients in the region where the
202 candidate is registered.

203
204 The OPTN Contractor will re-calculate the median allocation MELD at transplant
205 every 180 days using the previous 365-day cohort. If there have been fewer than 10
206 transplants in the DSA in the previous 365 days, the median MELD at transplant for
207 will be calculated for the region where the candidate is registered. At each 180 day
208 update, if the median MELD increases, candidates with existing standardized score
209 exceptions will be assigned the increased score to match the re-calculated median
210 MELD. However, if the median MELD decreases at the 180 day update, candidates

211 with existing standardized score exceptions will not be assigned a score to match the
212 re-calculated median until the candidate is due for an extension.

213
214 In order to be approved for an extension of this MELD or PELD score exception,
215 transplant hospitals must submit an exception extension request according to *Policy*
216 9.4.D: MELD or PELD Score Exception Extensions.

217
218 **9.4.C.iii Requirements for Familial Amyloid Polyneuropathy**
219 **(FAP) MELD or PELD Score Exceptions**

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

- 222 1. Either that the candidate is also registered on the waiting list for a heart
223 transplant, or has an echocardiogram performed within 30 days prior to
224 submission of the initial exception request showing the candidate has an ejection
225 fraction greater than 40 percent.
226 2. That the candidate can walk without assistance.
227 3. That a transthyretin (TTR) gene mutation has been confirmed.
228 4. A biopsy-proven amyloid.

229 A liver candidate at least 18 years old at the time of registration that meets the
230 requirements for a standardized MELD score exception will be assigned a score that
231 is 3 points below the median allocation MELD at transplant for liver recipients at least
232 18 years old in the DSA where the candidate is registered. If the candidate's
233 exception score would be higher than 34 based on this calculation, the candidate's
234 score will be capped at 34.

235
236 A liver candidate 12 to 17 years old at the time of registration that meets the
237 requirements for a standardized MELD score exception will be assigned a score
238 equal to the median MELD at transplant for all liver recipients in the DSA where the
239 candidate is registered.

240
241 A liver candidate less than 12 years old at the time of registration that meets the
242 requirements for a standardized PELD score exception will be assigned a score
243 equal to the median MELD at transplant for all liver recipients in the region where the
244 candidate is registered.

245
246 The OPTN Contractor will re-calculate the median allocation MELD at transplant
247 every 180 days using the previous 365-day cohort. If there have been fewer than 10
248 transplants in the DSA in the previous 365 days, the median MELD at transplant will
249 be calculated for the region where the candidate is registered. At each 180 day
250 update, if the median MELD increases, candidates with existing standardized score
251 exceptions will be assigned the increased score to match the re-calculated median
252 MELD. However, if the median MELD decreases at the 180 day update, candidates
253 with existing standardized score exceptions will not be assigned a score to match the
254 re-calculated median until the candidate is due for an extension.

255
256 In order to be approved for an extension of this MELD or PELD score exception,
257 transplant hospitals must submit an exception extension request according to *Policy*
258 9.4.D: MELD or PELD Score Exception Extensions and an echocardiogram that
259 meets *both* of the following criteria:

- 260
261 1. Shows that the candidate has an ejection fraction > 40 percent every six 6
262 months
263 2. Has been performed within 30 days prior to submission of the extension request

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**9.4.C.iv 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.D: MELD or PELD Score Exception Extensions*.

**9.4.C.v 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 allocation 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 allocation 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, if the median MELD increases, candidates with existing standardized score exceptions will be assigned the increased score to match the re-calculated median MELD. However, if the median MELD decreases at the 180 day update, candidates with existing standardized score exceptions will not be assigned a score to match the re-calculated median until the candidate is due for an extension.

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.D: MELD or PELD Score Exception Extensions*, and evidence that the

316 candidate's PaO₂ remained at less than 60 mmHg on room air within the 30 days
317 prior to submission of the extension request.

318
319 **9.4.C.vi Requirements for Metabolic Disease MELD or PELD**
320 **Score Exceptions**

321 A liver candidate less than 18 years old at the time of registration will receive a MELD
322 or PELD score exception for metabolic disease if the candidate's transplant hospital
323 submits evidence of urea cycle disorder or organic acidemia.

324
325 A liver candidate 12 to 17 years old at the time of registration that meets the
326 requirements for a standardized MELD score exception will be assigned a score
327 equal to the median MELD at transplant for all liver recipients in the DSA where the
328 candidate is registered. If the candidate does not receive a transplant within 30 days
329 of being registered with the exception score, then the candidate's transplant
330 physician may register the candidate as a status 1B.

331
332 A liver candidate less than 12 years old at the time of registration that meets the
333 requirements for a standardized PELD score exception will be assigned a score
334 equal to the median MELD at transplant for all liver recipients in the region where the
335 candidate is registered. If the candidate does not receive a transplant within 30 days
336 of being registered with the exception score, then the candidate's transplant
337 physician may register the candidate as a status 1B.

338
339 If a candidate has a metabolic disease other than urea cycle disorder or organic
340 acidemia, and the candidate's transplant program believes that a candidate's
341 MELD/PELD score does not appropriately reflect the candidate's medical urgency,
342 then the transplant physician may request an exception according to *Policy 9.4.A:*
343 *MELD or PELD Score Exception Requests.*

344
345 In order to be approved for an extension of this MELD or PELD score exception,
346 transplant hospitals must submit an exception extension request according to *Policy*
347 *9.4.D: MELD or PELD Score Exception Extensions.*

348
349 **9.4.C.vii Requirements for Portopulmonary Hypertension MELD**
350 **or PELD Score Exceptions**

351 A candidate will receive a MELD or PELD score exception for portopulmonary
352 hypertension if the candidate has a mean pulmonary arterial pressure less than 35
353 mmHg following intervention, and the transplant hospital submits evidence of *all* of
354 the following:

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

363 A liver candidate at least 18 years old at the time of registration that meets the
364 requirements for a standardized MELD score exception will be assigned a score that
365 is 3 points below the median allocation MELD at transplant for liver recipients at least
366 18 years old in the DSA where the candidate is registered. If the candidate's

367 exception score would be higher than 34 based on this calculation, the candidate's
368 score will be capped at 34.

369
370 A liver candidate 12 to 17 years old at the time of registration that meets the
371 requirements for a standardized MELD score exception will be assigned a score
372 equal to the median MELD at transplant for all liver recipients in the DSA where the
373 candidate is registered.

374
375 A liver candidate less than 12 years old at the time of registration that meets the
376 requirements for a standardized PELD score exception will be assigned a score
377 equal to the median MELD at transplant for all liver recipients in the region where the
378 candidate is registered.

379
380 The OPTN Contractor will re-calculate the median allocation MELD at transplant
381 every 180 days using the previous 365-day cohort. If there have been fewer than 10
382 transplants in the DSA in the previous 365 days, the median MELD at transplant will
383 be calculated for the region where the candidate is registered. At each 180 day
384 update, if the median MELD increases, candidates with existing standardized score
385 exceptions will be assigned the increased score to match the re-calculated median
386 MELD. However, if the median MELD decreases at the 180 day update, candidates
387 with existing standardized score exceptions will not be assigned a score to match the
388 re-calculated median until the candidate is due for an extension.

389
390 In order to be approved for an extension of this MELD or PELD score exception,
391 transplant hospitals must submit an exception extension request according to *Policy*
392 *9.4.D: MELD or PELD Score Exception Extensions* and perform a repeat heart
393 catheterization every three months that confirms the mean pulmonary arterial
394 pressure (MPAP) remains less than 35 mmHg.

395
396 **9.4.C.viii Requirements for Primary Hyperoxaluria MELD or PELD**
397 **Score Exceptions**

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

- 400 1. The candidate is registered for a combined liver-kidney transplant
401 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy
402 using sample analysis or genetic analysis
403 3. Estimated glomerular filtration rate (eGFR) by six variable Modification of Diet in
404 Renal Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by
405 iothalamate or iohexol, is less than or equal to 25 mL/min on 2 occasions at least
406 42 days apart

407
408 A liver candidate at least 18 years old at the time of registration that meets the
409 requirements for a standardized MELD score exception will be assigned a score
410 equal to the median allocation MELD at transplant for liver recipients at least 18
411 years old in the DSA where the candidate is registered. If the candidate's exception
412 score would be higher than 34 based on this calculation, the candidate's score will be
413 capped at 34.

414
415 A liver candidate 12 to 17 years old at the time of registration that meets the
416 requirements for a standardized MELD score exception will be assigned a score that
417 is 3 points above the median MELD at transplant for all liver recipients in the DSA
418 where the candidate is registered.

419

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

424
425 The OPTN Contractor will re-calculate the median allocation MELD at transplant
426 every 180 days using the previous 365-day cohort. If there have been fewer than 10
427 transplants in the DSA in the previous 365 days, the median MELD at transplant will
428 be calculated for the region where the candidate is registered. At each 180 day
429 update, if the median MELD increases, candidates with existing standardized score
430 exceptions will be assigned the increased score to match the re-calculated median
431 MELD. However, if the median MELD decreases at the 180 day update, candidates
432 with existing standardized score exceptions will not be assigned a score to match the
433 re-calculated median until the candidate is due for an extension.

434
435 In order to be approved for an extension of this MELD or PELD score exception,
436 transplant hospitals must submit an exception extension request according to *Policy*
437 *9.4.D: MELD or PELD Score Exception Extensions.*

438
439 **9.4.C.ix Requirements for Hepatocellular Carcinoma (HCC)**
440 **MELD or PELD Score Exceptions**

441 **9.3.F Candidates with Hepatocellular Carcinoma (HCC)**

442 Upon submission of the first exception request, a candidate that is:

- 443
- ~~At least 18 years old with Hepatocellular Carcinoma (HCC) and meets the criteria according to Policies 9.3.F.i through 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.~~ described below, will be provided a score according to *Extensions of HCC Exceptions.*
 - ~~Twelve to 17 years old, and the Regional National Liver Review Board (NLRB) 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.~~ provided a score according to *Extensions of HCC Exceptions.*
 - ~~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 41.~~ provided a score according to *Extensions of HCC Exceptions.*

444
445 **9.3.F.i Initial Assessment and Requirements for HCC Exception**
446 **Requests**

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

- 449
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
- 457
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460 The transplant hospital must maintain documentation of the radiologic images and
 461 assessments of all OPTN Class 5 lesions in the candidate's medical record. If growth
 462 criteria are used to classify a lesion as HCC, the radiology report must contain the
 463 prior and current dates of imaging, type of imaging, and measurements of the lesion.

464
 465 For those candidates who receive a liver transplant while receiving additional priority
 466 under the HCC exception criteria, the transplant hospital must submit the *Post-*
 467 *Transplant Explant Pathology Form* to the OPTN Contractor within 60 days of
 468 transplant. If the pathology report does not show evidence of HCC, the transplant
 469 hospital must also submit documentation or imaging studies confirming HCC at the
 470 time of assignment. The Liver and Intestinal Organ Transplantation Committee will
 471 review a transplant hospital when more than 10 percent of the HCC cases in a one-
 472 year period are not supported by the required pathologic confirmation or submission
 473 of clinical information.

474
 475 **9.3.F.ii—Eligible Candidates Definition of T2 Lesions**

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

- 479 • One lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- 480 • Two or three lesions each greater than or equal to 1 cm and less than or equal to
- 481 3 cm in size.
- 482
- 483

484 **9.3.F.iii—Lesions Eligible for Downstaging Protocols**

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

- 487 • One lesion greater than 5 cm and less than or equal to 8 cm
- 488 • Two or three lesions each less than 5 cm and a total diameter of all lesions less
- 489 than or equal to 8 cm
- 490 • Four or five lesions each less than 3 cm and a total diameter of all lesions less
- 491 than or equal to 8 cm
- 492
- 493

494 For candidates who meet the downstaging criteria and then complete local-regional
 495 therapy, their residual lesions must subsequently meet the requirements for T2
 496 lesions according to ~~Policy 9.3.F.ii: Eligible Candidates Definition of T2 Lesions~~ to be
 497 eligible for a standardized MELD exception. Downstaging to meet eligibility
 498 requirements for T2 lesions must be demonstrated by CT or MRI performed after
 499 local-regional treatment. Candidates with lesions that do not initially meet the
 500 downstaging protocol inclusion criteria who are later downstaged and then meet
 501 eligibility for T2 lesions are not automatically eligible for a standardized MELD
 502 exception and must be referred to the NLRRB for consideration of a MELD exception.

503
 504 **9.3.F.iv—Candidates with Alpha-fetoprotein (AFP) Levels Greater than**
 505 **1000**

506 Candidates with lesions meeting T2 criteria according to ~~Policy 9.3.F.ii Eligible~~
 507 ~~Candidates Definition of T2 Lesions~~ but with an alpha-fetoprotein (AFP) level greater
 508 than 1000 ng/mL may be treated with local-regional therapy. If the candidate's AFP
 509 level falls below 500 ng/mL after treatment, they are eligible for a standardized MELD
 510 exception. Candidates with an AFP level greater or equal to 500 ng/mL following
 511 local-regional therapy at any time must be referred to the NLRRB for consideration of
 512 a MELD exception.

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9.3.F.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—Imaging Requirements for Class 5 Lesions

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

Table 9-52: Classification System for Nodules Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study
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.

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9.3.F.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.

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

542
 543 The OPTN Contractor will re-calculate the median allocation MELD at transplant
 544 every 180 days using the previous 365-day cohort. If there have been fewer than 10
 545 transplants in the DSA in the previous 365 days, the median MELD at transplant will
 546 be calculated for the region where the candidate is registered. At each 180 day
 547 update, if the median MELD increases, candidates with existing standardized score
 548 exceptions will be assigned the increased score to match the re-calculated median
 549 MELD. However, if the median MELD decreases at the 180 day update, candidates
 550 with existing standardized score exceptions will not be assigned a score to match the
 551 re-calculated median until the candidate is due for an extension.

552
 553 A liver candidate less than 18 years old at the time of registration that meets the
 554 requirements for a standardized MELD or PELD score exception will be assigned a
 555 MELD or PELD score of 40.

556
 557 Exception scores for candidates that were at least 18 years old upon submission of
 558 their initial exception request are assigned according to *Table 9-4* below. The
 559 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

563
 564 If a candidate was less than 18 years old upon submission of their initial exception
 565 request, the candidate will receive additional MELD or PELD points equivalent to a
 566 10 percentage point increase in the candidate’s mortality risk every three months
 567 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

Exception Request	MELD or PELD Exception Score
5th extension	MELD 39 or PELD 56
6th extension	MELD 40 or PELD 60

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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

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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.

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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 NLRRRB review, even if the estimated size of residual viable tumors falls below stage T2 criteria due to ablative therapy.

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

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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.

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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.

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9.3.D—Pediatric Liver Candidates with Metabolic Diseases

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~~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.~~

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~~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.~~

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9.3.E—Candidates with Cholangiocarcinoma

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614

~~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:~~

- 615
616 1. ~~Submit a written protocol for patient care to the Liver and Intestinal Organ Transplantation~~
617 ~~Committee that must include all of the following:~~
618 ~~a. Candidate selection criteria~~
619 ~~b. Administration of neoadjuvant therapy before transplantation~~
620 ~~c. Operative staging to exclude any patient with regional hepatic lymph node metastases,~~
621 ~~intrahepatic metastases, or extrahepatic disease~~
622 ~~d. Any data requested by the Liver and Intestinal Organ Transplantation Committee~~
623
624 2. ~~Document that the candidate meets the diagnostic criteria for hilar CCA with a malignant~~
625 ~~appearing stricture on cholangiography and one of the following:~~
626 ~~a. Biopsy or cytology results demonstrating malignancy~~
627 ~~b. Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis~~
628 ~~c. Aneuploidy~~
629 ~~The tumor must be considered unresectable because of technical considerations or~~
630 ~~underlying liver disease.~~
631 3. ~~If cross-sectional imaging studies demonstrate a mass, the mass must be less than three cm.~~
632 4. ~~Intrahepatic and extrahepatic metastases must be excluded by cross-sectional imaging~~
633 ~~studies of the chest and abdomen at the time of the initial application for the MELD/PELD~~
634 ~~exception and every three months before the MELD/PELD score increases.~~
635 5. ~~Regional hepatic lymph node involvement and peritoneal metastases must be assessed by~~
636 ~~operative staging after completion of neoadjuvant therapy and before liver transplantation.~~
637 ~~Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable~~
638 ~~to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.~~
639 6. ~~Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound,~~
640 ~~operative or percutaneous approaches) must be avoided because of the high risk of tumor~~
641 ~~seeding associated with these procedures.~~
642

9.34.GD MELD or /PELD Score Exception Extensions

644 Transplant hospitals may apply for ~~submit a MELD or PELD score exception extension~~
645 ~~MELD/PELD Exception Score Request Form to the NLRB to receive the equivalent of a 10~~
646 ~~percentage point increase in candidate mortality every 90 days. 3 months as long as the~~
647 ~~candidate continues to meet the exception criteria. Extensions must be prospectively reviewed by~~
648 ~~the RRB.~~
649

650 A candidate's approved exception score will be maintained if the transplant hospital enters the
651 extension application ~~request more than between 3 and 30 days before the due date according to~~
652 ~~Table 9-1: Liver Status Update Schedule, even if the RRB NLRB does not act before the due~~
653 ~~date. If the extension application request is later denied then the candidate will be assigned the~~
654 ~~calculated MELD or PELD score based on the most recent reported laboratory values.~~
655

OPTN Bylaws

9.3 Regional Review Boards

658 ~~Each region establishes regional~~The OPTN establishes review boards (RRBs) for specific organs as
659 ~~necessary to review requests for exceptions that are permitted by policy. These review boards RRBs~~
660 provide confidential medical peer review of transplant candidates placed on the waiting list at a more
661 urgent status than the standard listing criteria justifies. As part of these reviews, RRBs review boards may
662 perform the following tasks:
663

- 664 ■ Review justification forms submitted by the transplant hospital that document the candidate's current
665 condition and decide if the requested status is appropriate.

666 ■ Refer transplant hospitals to the appropriate OPTN Committee for review of candidates listed and
667 transplanted at an inappropriate status. The Committee may then, if necessary, refer the hospital to
668 the Membership and Professional Standards Committee (MPSC).

669 ■ Serve other peer review functions as determined by the Board of Directors.

670

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

675

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

681

682 **Appendix M: Definitions**

683 **Regional Review Boards (RRBs)**

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

689

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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 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 alternate will fulfill the responsibilities of the representative.

If a representative or alternate does not vote on an open request within 7 days on three separate instances within a 12 month period, the Chair will remove the individual from the NLRB. If a representative or alternate does not vote because a case is approved and closed before the 7 day timeframe expires, it is not considered a failure to vote. A representative or alternate who has been removed for failure to perform the duties required is not eligible to serve again for 3 years.

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

4. Voting Procedure

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

As part of the MELD/PELD Exception program in UNetSM, NLRB members are notified of new cases by email. To access the exception request, click on the emailed link or go to <https://www.unet.unos.org/>. Log-in using your UNetSM username and password and click on "Waitlist," then "NLRB."

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

5. Appeal Process

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

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

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

Appeals Review Team (ART)

At the beginning of each new service term, nine NLRB members are randomly assigned to serve each month of the year on the ART. There may be multiple ARTs, depending on the volume of cases. An NLRB member will be selected to serve for no more than one month each year on the ART. The ART meets via conference call at the same day and time each week; however calls may be rescheduled in advance to accommodate federal holidays.

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

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

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

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

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