OPTN

Briefing to the OPTN Board of Directors on

Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution

OPTN Lung Transplantation Committee

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OPTN

Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution

Affected Policies:	*10.2.C: Review of Exceptions* *10.2.D: Appeals to Lung Review Board* *10.2.E: Appeals to Lung Transplantation Committee*
Affected Guidelines:	*Lung Review Board Guidelines*
Sponsoring Committee:	*Lung Transplantation*
Public Comment Period:	*August 3, 2022-September 28, 2022*
Board of Directors Meeting:	*December 5, 2022*

Executive Summary

The Board of Directors approved significant lung allocation changes in December 2021, with the passage of *Establish Continuous Distribution of Lungs*.[1] That change included a Lung Review Board to evaluate exception requests for the new lung composite allocation score (CAS), which incorporates:

- Medical urgency
- Post-transplant outcomes
- Candidate biology
- Patient access
- Placement efficiency

This proposal would establish the operational guidelines for the Lung Review Board when reviewing candidates' requests for exceptions for their lung CAS. It would also establish clinical guidelines for transplant programs who wish to submit an exception request, and for Lung Review Board members who review such requests. Although exceptions are non-standard circumstances by their nature, the guidelines and guidance are intended to provide as much standardization as is appropriate for the review of such requests.

Furthermore, the OPTN intends to establish an exception review framework that is consistent across organs and candidates. This proposal would make policy changes to improve consistency across organs in terms of where members can find information on review boards between operational guidelines, guidance, and policy.

[1] "Establish Continuous Distribution of Lungs," OPTN, Notice of OPTN Policy Changes, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

Purpose

To promote a consistent review of exception requests under continuous distribution, the Lung Transplantation Committee (Committee) proposes the adoption of:

1. Operational guidelines that outline representation, responsibilities, and process for the Lung Review Board (Review Board)
2. Clinical guidance regarding information that transplant programs should provide when submitting an exception request, and that review board members should consider when evaluating an exception request
3. Policy changes to improve consistency across organs in terms of where members can find information on review boards between operational guidelines, guidance, and policy

Background

Current lung allocation policy allows transplant programs to request approval for a specific priority or lung allocation score (LAS) for candidates if the transplant program believes that a candidate's current priority or LAS does not appropriately reflect the candidate's medical urgency for transplant (per OPTN *Policy 10.2 Priority and Score Exceptions*). These requests are referred to as exception requests, since transplant programs are requesting an adjustment to the candidate's allocation priority as assigned per policy. The Review Board reviews either approves or denies the exception requests. Requirements and processes for the Review Board are delineated in OPTN Policies and in operational guidelines.[2]

The Board of Directors approved significant lung allocation changes in December 2021, with the passage of *Establish Continuous Distribution of Lungs*.[3] The approved changes will replace the LAS with a lung composite allocation score (CAS). Whereas the LAS accounts for estimated waiting list survival and post-transplant outcomes for lung candidates, the lung CAS accounts for those factors as well as candidate biology, patient access, and placement efficiency in one composite score. The approved policy changes also included a Review Board to evaluate requests for exceptions to components of the lung CAS. The Committee requested feedback on the composition and function of the Review Board as part of the public comment proposal for continuous distribution, and this proposal incorporates that feedback.

As with the current system, the new Review Board will review exception requests for candidates whose score may not appropriately prioritize them for transplant. Exceptions may be requested for any components of the score that can be determined before the match run: waiting list survival, post-transplant outcomes, candidate biology, and patient access. Exceptions will not be available for placement efficiency, since points for placement efficiency are calculated at the time the match run is executed, based on the location of the donor. Since this component of the score is not based solely on a candidate characteristic, and does not stay stable, the Committee did not anticipate a justification for a placement efficiency exception that would apply to all match runs with that candidate. Exceptions will be reviewed prospectively by the Review Board, and exceptions will not expire.

While the continuous distribution proposal established the new Review Board in policy, it did not provide operational guidelines for the review board or clinical guidance for submitting exception requests, which are instead addressed in this proposal.

[2] "Lung Review Board Information," OPTN, January 2015, accessed October 14, 2022, https://optn.transplant.hrsa.gov/media/2701/review_board_guidelines_lung.pdf.
[3] Ibid.

Proposal for Board Consideration

The Committee proposes operational guidelines for the Review Board, including review board composition, voting, and appeals; clinical guidance on exception requests for transplant programs and Review Board members; and policy changes to align OPTN resources related to the Review Board for lung with those of other organs.

Operational Guidelines: Review Board Composition

Reviewer Rotation and Representation

The current Review Board is comprised of representatives from nine lung transplant programs. The Committee proposes having representatives from thirteen lung transplant programs on the new Review Board, with each of the thirteen transplant programs appointing a primary review board member and an alternate. The Committee originally proposed having representatives from twelve lung transplant programs, but decided to add a thirteenth program following public comment in order to include an additional pediatric reviewer.

The review boards for liver and heart provide an opportunity for each active transplant program for the organ to participate. However, compared to liver or heart, there have historically been fewer requests for exceptions for lung candidate scores. Due to the smaller numbers, the Committee proposes a 5-year rotation as depicted in **Figure 1**, rather than offering opportunities to all lung transplant programs to be represented on the review board at all times. Each year, approximately 1/5 of active lung transplant programs would have an opportunity to appoint a review board member and alternate to the Review Board. The representatives would serve a term of 2 years, and then the program would not have representatives for the next 3 years. After that, the transplant program would have an opportunity to appoint a representative and alternate again. This would allow for some continuity in the review board as members roll off and new members roll on, since only half of the review board members will be changing each year.

Figure 1: Illustration of Term Rotation

	Year 1	Year 2	Year 3	Year 4	Year 5
1st Cohort					
2nd Cohort					
3rd Cohort					
4th Cohort					
5th Cohort					

The number of members on the review board, the specific transplant programs in each cohort, and the specific rotation of five years, are not detailed in the proposed guidelines. This is intentional in order to allow the Committee the flexibility to increase the number of review board members, increase the percentage of lung programs allowed to rotate on, or to adjust the timing of a cohort as new programs are added or inactivated. This allows more flexibility in the event that there are significant changes in the exception case volume due to the introduction of the composite allocation score, or due to other changes in the future. It also ensures that a rotation is maintained, even if such changes are needed.

There are currently 72 active lung programs.[4] This would result in 14 or 15 programs in each cohort. Since each cohort would serve for 2 years, and the terms would overlap, this rotation would result in 28

[4] OPTN data as of October 25, 2022.

to 30 transplant programs eligible to have representatives on the Review Board at any point in time. Each year, OPTN staff will reach out to the 28-30 programs in the designated cohorts to request volunteers to serve on the Review Board, and will accept as many transplant programs as needed to fill the vacancies.

Representatives

Consideration of exception cases requires an understanding of lung disease and lung transplantation. In order to ensure that the review board members adjudicating lung exception cases have a sufficient minimum understanding, the Committee proposes that the primary representative must have at least five years of post-training transplant experience and the alternate representative must have at least three years of post-training transplant experience.[5] Transplant programs must ensure that Review Board volunteers from their programs meet these requirements when submitting volunteers. Following public comment, the Committee decided to include this in the operational guidelines as a requirement.

The lower requirement for alternate representatives is intended to allow an opportunity for those with less experience to serve on the review board and learn. The alternates are less likely to be appointed to an exception case, since primary review board members will be assigned to cases unless they indicate they are out of the office. This mitigates the risk in allowing alternates with less transplant experience to review exception requests.

Case Assignment

As with the other organ review boards, for each exception submitted, a subset of the Review Board members currently serving would be assigned to the case. The Committee proposes assigning nine reviewers to each exception request via random selection. The system would automatically exclude reviewers from the submitting center when assigning reviewers to avoid conflict of interests. Primary reviewers would have the option to report when they will be out of the office. In those cases, their alternate would have the opportunity to be assigned exception cases in their place. Cases will not be sent to the primary and alternate reviewers at the same time. This case assignment approach is more similar to the liver[6] and pediatric heart review boards,[7] which have larger review boards and assign cases to a smaller subset of review board members. This approach would allow for system efficiencies in implementation, and more consistency in review board operations across organs. Following public comment, the Committee clarified in the operational guidelines that alternate representatives will only be assigned cases when the primary representative indicates they are out of the office.

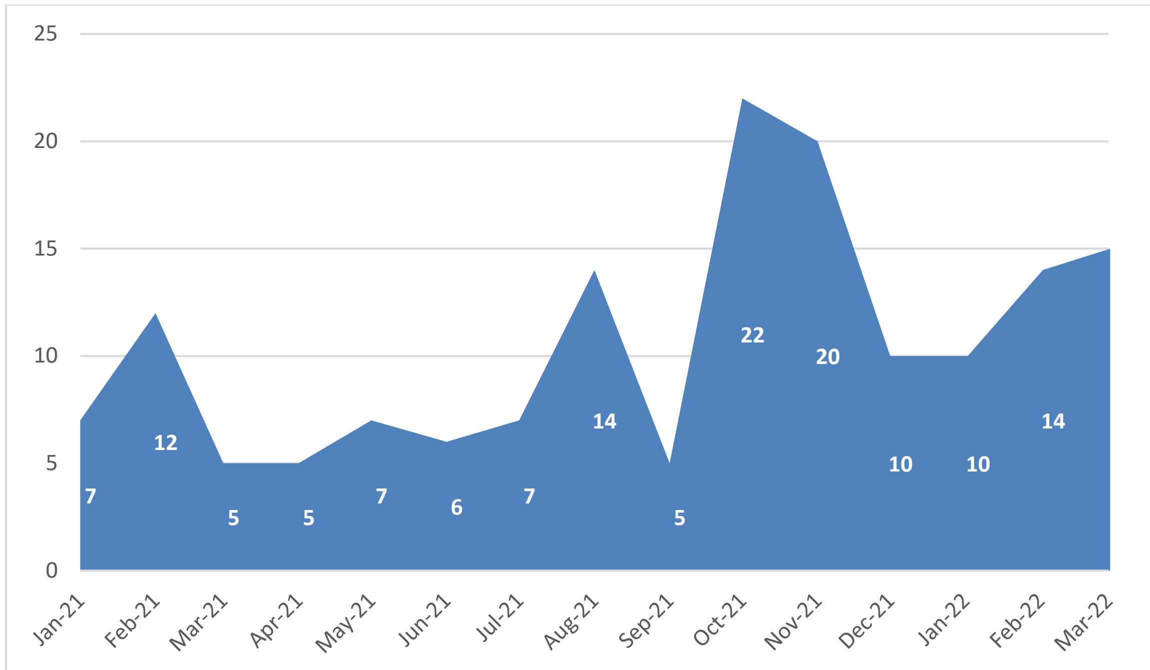
In selecting the number of reviewers to assign per case, the Committee considered that review board members who do not receive assignments frequently enough may not be as likely to respond quickly to cases, or they may not be comfortable reviewing exception cases if they have not yet seen sufficient examples of the other types of exceptions that are being approved or denied by the Review Board. The Committee was not as concerned with the possibility of assigning too many cases to reviewers based on the relatively low volume of lung exception cases, as seen in **Figure 2**.

[5] Lung Transplantation Committee, OPTN, Meeting Summary for May 13, 2022, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/uo1jchw4/20220513_lung-committee-meeting-summary.pdf.

[6] "National Liver Review Board Operational Guidelines," OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/ywxddona/20200804_nlrb_operational_guidelines.pdf.

[7] "National Heart Review Board for Pediatrics," Policy Notice, OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/3841/2020-06_thoracic_nhrb_for_pediatrics_policy_notice.pdf.

Figure 2: Number of Exceptions Submitted Each Month, January 2021 – March 2022[8]



Historically, there have been between 5 and 22 lung exception cases each month, as shown above. Accordingly, the Committee determined that assigning nine reviewers per case will strike the appropriate balance of providing reviewers the opportunity to review cases without overwhelming members with the volume of cases. While assignment to cases is random in the sense that the system will not follow the same order every time, the system will consider reviewer case load when assigning cases so as to distribute the workload across reviewers.

Pediatric Representation

Review of exception requests for pediatric candidates often requires specific pediatric experience and expertise. The Committee has received feedback from past review board members that pediatric expertise is essential for reviewing these cases.[9] The Committee proposes ensuring that at least four pediatric programs are represented on the Review Board at any given time, out of the thirteen transplant programs represented. This is a change from the public comment proposal, which called for three pediatric programs represented at a time, to respond to public comment feedback with concerns about the level of pediatric representation on the Review Board.

Following public comment, the Committee also clarified that in order to be considered a pediatric representative on the Review Board, the transplant program must have performed at least one transplant for a candidate under the age of 12 within the last five years. Previously, the guidelines had indicated that any transplant program with an active pediatric lung transplant component could be considered pediatric representatives. While there are 40 transplant programs that have active pediatric lung transplant components,[10] there are no specific membership requirements for pediatric lung

[8] OPTN, Lung Review Board, HRSA Quarterly Reports, January 2021 – April 2022.
[9] Lung Transplantation Committee, OPTN, Meeting Summary for May 13, 2022, accessed June 13, 2022, https://optn.transplant.hrsa.gov/media/uo1jchw4/20220513_lung-committee-meeting-summary.pdf.
[10] OPTN data as of October 17, 2022.

transplant components,[11] and only 11 of those 40 programs currently have pediatric candidates listed.[12] The Committee noted that many of these programs have active pediatric lung components because they perform transplants for older adolescents (e.g. patients who are 16 or 17 years old) but that they would not consider these programs to have expertise in performing lung transplants for young children. The Committee added the requirement to have performed at least one lung transplant for a candidate under the age of 12 due to the unique physiological challenges of performing lung transplants in younger children. The Committee estimates that 8-10 lung transplant programs would meet these requirements, so these lung transplant programs would be represented on the Review Board more frequently than other lung transplant programs. The proposed five-year rotation would ensure that this minimum threshold for pediatric representation is reached. The Review Board members from such pediatric programs would be given priority for assignment to pediatric cases as long as both the primary and alternate from those transplant programs have not reported that they are out of the office.

Chair

The Committee proposes including a Chairperson for the Review Board. This position will be modeled after the National Liver Review Board Chair,[13] who is responsible for ensuring that review board members are actively participating and removing those who are not.

The Committee also proposes following the liver model in having the immediate past chair of the OPTN committee as the Chair of the review board. The Committee expects that having a review board Chair who has recent OPTN committee experience and currently serves on the Committee in an ex officio role will improve communication between the two groups. It will provide an opportunity for the review board members to provide feedback to the Committee on opportunities for improvement, and a way for the Committee to provide feedback to the review board on areas in which they may expect changes.

Following public comment, the Committee decided that the Chair should not be a voting member so that the Chair could serve in more of an advisory and support capacity, rather than as a representative of their own transplant program. Accordingly, the Chair would not have any special voting privileges or the ability to break ties. Instead, the Chair is expected to serve as a liaison between the Review Board and the Committee. The Chair will also convene regular meetings of review board and Committee members leading up to and following implementation of continuous distribution of lungs in order to train members on changes to the exception process, answer questions, and identify any issues that should be brought to the Committee for action. This Lung Review Board Subcommittee will review redacted clinical narratives during the first three months following implementation in order to identify if the Committee should provide additional guidance or education to lung transplant programs on exception requests.

Operational Guidelines: Voting

A five-day timeframe for review of all exception cases was established with a policy change in the proposal to *Establish Continuous Distribution of Lungs* approved in December 2021.[14] As shown in **Figure 3** and **Table 1**, most exception cases are processed within five days. The Committee does not propose changing that timeframe here, but proposes to move the timeframe requirement from policy into the

[11] OPTN Bylaws, accessed October 25, 2022. https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf
[12] Ibid.
[13] "National Liver Review Board Operational Guidelines," OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/ywxddona/20200804_nlrb_operational_guidelines.pdf.
[14] "Establish Continuous Distribution of Lungs," OPTN, Notice of OPTN Policy Changes, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

operational guidelines to streamline and avoid duplicating language. This will help with maintaining the language if future changes are made.

Figure 3: Distribution of Lung Review Board Process Times for Exceptions Requested January 1, 2022 – March 31, 2022[15]

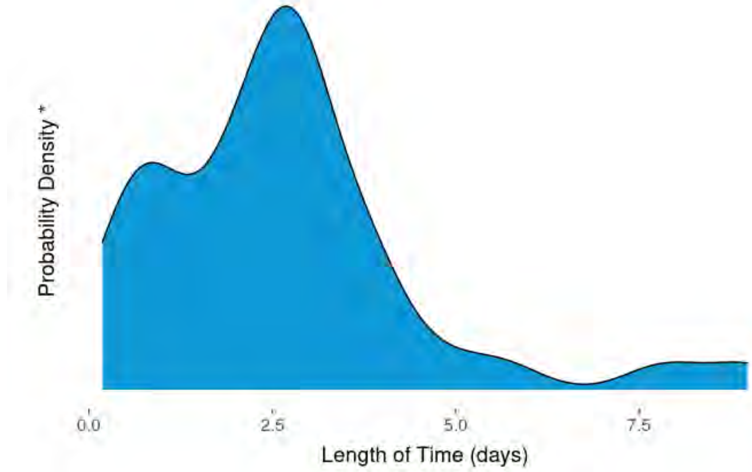


Table 1. Lung Exception Cases between January 20, 2021, to October 14, 2022

Total number of cases	313
Average time to close	2.07 days
Cases closed without a majority being reached	21
Cases closed without a quorum being met	0

In cases where there is no majority by the end of the third day, the votes that have been cast to that point would be retained, but any voters who have not responded will be removed from the case, and review board members from other transplant programs will be asked to vote in their place. This is also a change from the current system, in which either the reviewer or their alternate can vote at that point. By moving the vote to a new reviewer, the Review Board will better align with the other organ review boards, and this approach will improve clarity on who should be voting at any point in a case.

The Committee proposes that if there are no votes on a case after five days or if there is a tie among the votes cast, then the candidate would receive the exception requested. This is due to the Committee's preference not to disadvantage a candidate because of delay in voting or a tie among review board members. Given that exception requests are submitted when a transplant program has reason to believe that the patient's calculated score does not provide adequate access to transplant, this approach promotes access to transplant by aligning with the ethical principle of justice, which requires that potential recipients are given an equal opportunity to receive an organ when in need.[16]

[15] OPTN, Lung Review Board, HRSA Quarterly Report, April 2022. High probability density values mean that a high percentage of the population lies at or around the corresponding x-axis value, and vice versa. There were 0 missing values due to missing time points.
[16] "Ethical Principles in the Allocation of Human Organs," OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-in-the-allocation-of-human-organs/.

If the majority of votes submitted are to approve the exception, then the request is approved. If the majority of votes submitted are to deny the exception, then the request is denied. This means that if only one vote is submitted within the five-day review period, and that vote is to deny the exception, then the request is denied based on that one vote. However, as shown in **Figure 3** and **Table 1**, most exception requests are processed well within the seven-day review period granted by current policy, which means that all review board members voted. Accordingly, the Committee does not expect that exception cases will be determined based on one vote, but the Committee will monitor review board process times. Additionally, in the unlikely event that one vote denied an exception request, the case could be appealed back to the broader Review Board, and again to the Committee.

There is also a small chance that a situation could arise in which zero reviewers are available to review a request. Reasons for which a reviewer would not be available to review a case include if the reviewer indicates they are out of the office, if the reviewer loses OPTN Computer System access, or if the reviewer has a conflict of interest in reviewing the request. In the event that zero reviewers are available to review an exception request, the OPTN will monitor reviewer availability throughout the five-day review period and assign reviewers to the case as they become available. In the event that no reviewers became available during the five-day review period, the exception request would be approved.

Following public comment, the Committee replaced references in the guidelines “not to approve” exceptions with “to deny” in order to align the language in the guidelines with the voting options that review board members will see in the system when voting on exception requests.

Operational Guidelines: Appeals

In the event that a reviewer votes to deny an exception, that reviewer would be expected to provide useful feedback with the denial, including the reasons for denial. This feedback would be provided to the requesting transplant program. The transplant program would have the opportunity to appeal the decision, and may amend the requested exception at that time. Any appeal must be submitted within seven days after the denial.

On the first appeal, the exception would be returned to the same group of reviewers who initially denied the exception request. This would allow the transplant program to respond to any feedback provided by those review board members, and the reviewers to evaluate in light of their initial reasons for denial. Voting on the appeal would be conducted with the same rules as the initial review.

If the exception is denied again on appeal, the transplant program would have one more opportunity for appeal. The next appeal would be to the Committee, and would also need to be submitted within seven days of receipt of the denial. The Committee would review the appeal no later than fourteen days following the request to the Committee. This was a change in response to public comment feedback, as the public comment proposal indicated that the Committee would review appeals at or no later than their next scheduled meeting. Public comment feedback recommended reviewing appeals within 14 days and the Committee agreed. In practice, the Committee will aim to review appeals within 7 days, but will ensure appeals are reviewed no later than 14 days following the request in accordance with the policy. The Committee also updated the operational guidelines following public comment to indicate that the transplant program may also amend their exception request in their appeal to the Committee, as well as in their first appeal to the Review Board.

Furthermore, the Committee updated the operational guidelines following public comment to indicate any member of the Committee who reviewed the case as a Review Board representative must abstain from voting on the appeal to the Committee. This is to avoid a scenario in which the same individual

could vote on both an initial appeal to the Review Board for a denied request and on a second appeal to the Committee.

Clinical Guidance

The Committee proposes guidance for transplant programs around what types of information to include in an exception request, and proposes updated guidance for exceptions for candidates with pulmonary hypertension.

The Committee's proposed guidance for pulmonary hypertension is an update to the existing guidance for pulmonary hypertension (PH).[17] The existing guidance advises transplant programs to request the 90th percentile lung allocation score (LAS) for PH candidates meeting clinical criteria (patient deteriorating on optimal therapy, and right atrial pressure greater than 15 mmHg *or* cardiac index less than 1.8 $L/min/m^2$).[18] The Committee proposes retaining the same criteria, but updating the recommended score. Under the continuous distribution system, the Committee recommends a request for the 90th percentile of the waiting list survival and post-transplant outcomes components of the lung CAS. These scores are most similar to the underlying parts of the LAS, so the Committee proposes that this is the best approach to carry forward the intent of the original guidance in the continuous distribution framework. The national distribution of waiting list survival and post-transplant outcomes scores, including the 90th percentiles, will be posted online and updated monthly to assist members in submitting these exception requests.

Based on public comment feedback, the Committee also added guidance on how to request a pediatric priority 1 equivalent score for pediatric candidates in the new allocation system.

Policy Changes

The policy changes for the Review Board outlined in the continuous distribution proposal stated that if the Review Board fails to make a decision on either an initial exception request or an appeal by the end of a five-day period, then the candidate will be assigned the requested exception score. As noted above, the Committee proposes striking this language from policy and instead including this information in the operational guidelines. The operational guidelines outline the voting procedures and describe whether or not a request will be approved based on various voting scenarios, so the Committee determined that it was duplicative and potentially confusing to include this information in the policy language as well. This change is consistent with the OPTN's efforts to standardize review board processes across organs and how this information is presented for the National Heart Review Board for Pediatrics.[19]

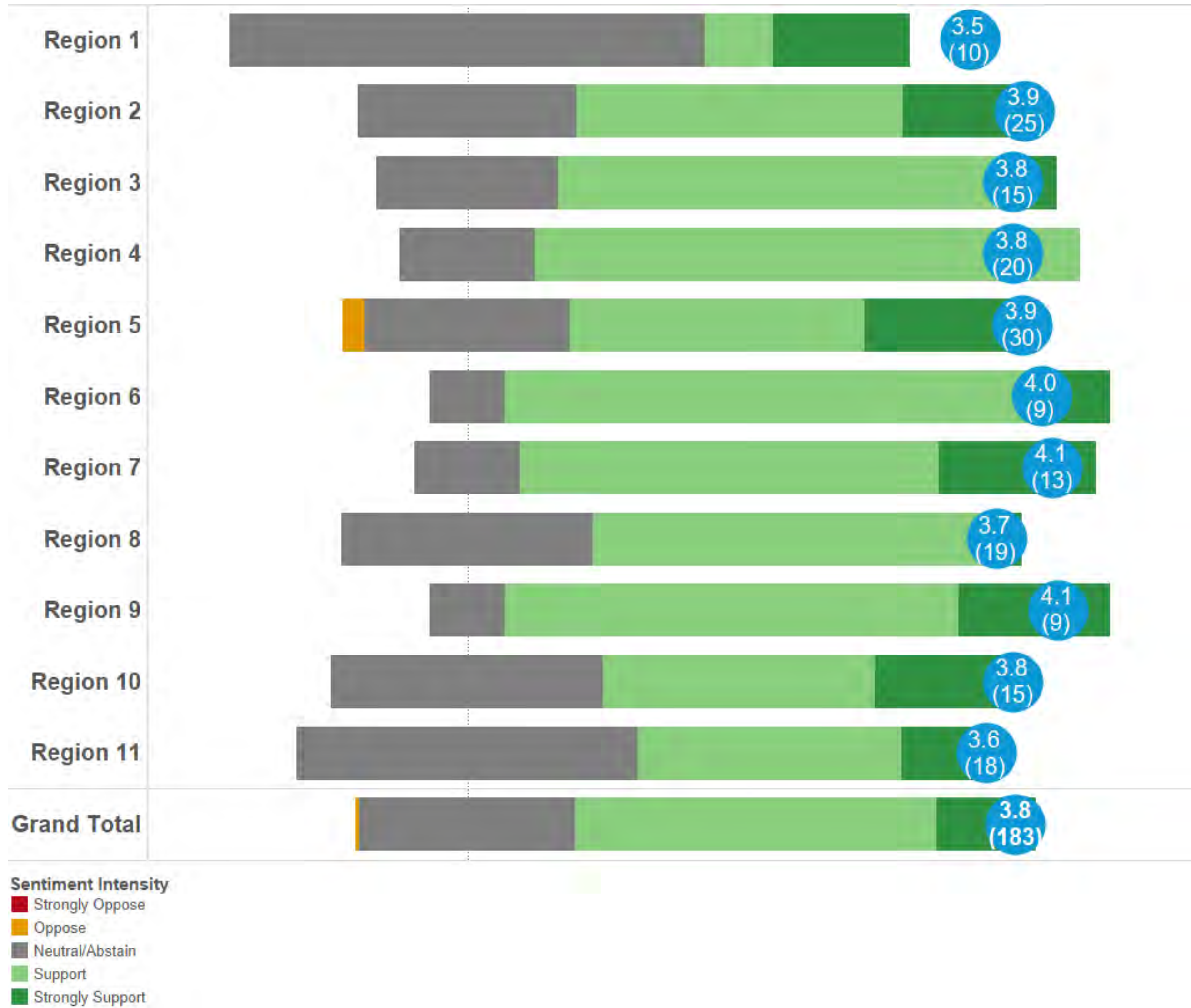
Additionally, the Committee proposes that if the Review Board denies an exception request on appeal, then the candidate's transplant program may appeal to the Lung Transplantation Committee within seven days of receiving the denial, rather than fourteen days. This change is consistent with the timeline for appealing exception requests to the Review Board, and with the appeals process for the National Liver Review Board as delineated in *Policy 9.4.B NLRB and Committee Review of MELD or PELD Exceptions*. Finally, the Committee proposes updating the policy to indicate that the Committee will review appeals within 14 days of receiving the request, as recommended in public comment.

[17] "History of the Pulmonary Hypertension Guidelines Distributed by the OPTN Contractor," OPTN, accessed June 14, 2022, https://unos.org/wp-content/uploads/UNetSM-System-Notice_PH_Guidelines_UNOS_Communications.pdf.
[18] "Submitting LAS exception requests for candidates diagnosed with PH," UNOS, accessed June 14, 2022, https://unos.org/news/submitting-las-exception-requests-for-candidates-diagnosed-with-ph/.
[19] "National Heart Review Board for Pediatrics," Policy Notice, OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/3841/2020-06_thoracic_nhrb_for_pediatrics_policy_notice.pdf.

Overall Sentiment from Public Comment

Committee members presented the proposal to four committees for feedback, and this proposal was on the non-discussion agenda for the regional meetings. A video presentation describing the proposal was posted to the OPTN website. Three professional organizations as well as a transplant hospital also provided written public comments. Most of the feedback supported the proposal, though one respondent indicated opposition. The proposal collected sentiment from 210 respondents, including 8 written comments. Sentiment is detailed below **in Figures 4 and 5**:

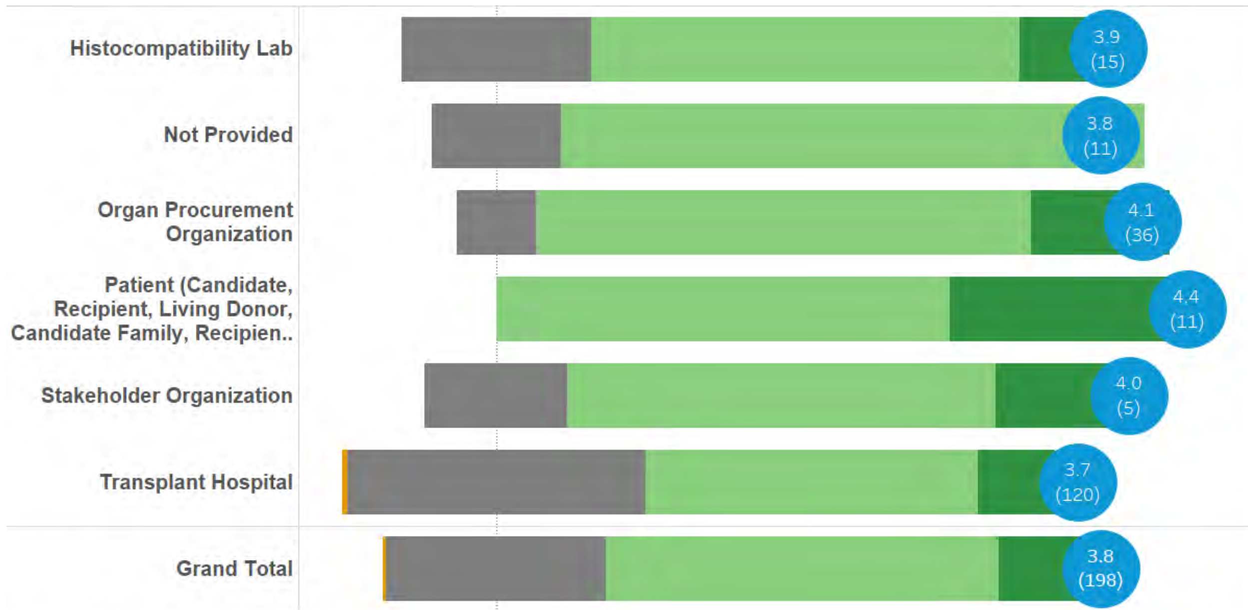
Figure 4: Regional Sentiment, Lung Review Board Proposal, 2022[20]'



The proposal was supported across the 11 regional meetings overall, though one respondent in Region 5 indicated they opposed the proposal because they felt that more pediatric representation is needed to review exceptions for pediatric candidates.

[20] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Figure 5: Sentiment by Member Type, Lung Review Board Proposal, 2022[21]



The proposal was supported across member types, though the transplant hospital representative from Region 5 opposed the proposal for the reason stated above.

Public comment feedback included suggestions for changes, primarily on managing pediatric exception requests and other review board operations.

Pediatric Exception Requests

Several comments supported providing guidance on requesting pediatric priority 1 exceptions. The Committee added such guidance as a post-public comment change.

The Pediatric Committee and other respondents recommended ensuring that review board members with the appropriate expertise handle exception requests for pediatric candidates. The Pediatric Committee expressed concern about reviewers without pediatric experience voting on pediatric cases, and the likelihood that pediatric reviewers on a pediatric case would be the minority. The Pediatric Committee suggested establishing a separate pediatric lung review board, or adding more pediatric experts to the existing review board and assigning pediatric specialists only to pediatric cases. The Organization for Donation and Transplant Professionals (NATCO) also supported establishing a separate pediatric review board. Another comment recommended ensuring that there are at least three pediatric reviewers per case.

The Committee considered establishing a separate pediatric review board but were concerned about the possibility that there may be only one or two reviewers available at a time to review a case, given the small number of transplant programs with expertise in pediatric lung transplantation, and because pediatric experts would not be able to vote on requests from their own transplant programs. The Committee also holds that there is value in including adult experts with pediatric experts in the review

[21] Ibid.

of pediatric exception requests, given that adult and pediatric candidates are all prioritized on the same match run for donors of all ages in continuous distribution. The Committee noted that the volume of exception requests for pediatric candidates is very low, with only one such request for a candidate under the age of 12 in the last two years, so a separate pediatric review board may not be needed. The Committee also considered structuring the review board process so that only five reviewers would be assigned to pediatric cases, to ensure that pediatric reviewers would likely make up the majority of reviewers for those cases. This change was determined out of scope for this proposal. Accordingly, the Committee intends to closely monitor pediatric exception requests following implementation, particularly whether those cases are being decided by primarily pediatric or adult reviewers, to determine if further changes are needed via a follow-on proposal.

The American Society of Transplantation (AST) and a member from Region 8 recommended ensuring that pediatric representatives have real and contemporary pediatric experience, for example, have performed at least five pediatric transplants in the last five years, and that at least one of the pediatric representatives has experience with infant lung transplant. The Committee responded to this feedback by adding the requirement for transplant programs to have performed at least one lung transplant for a pediatric candidate under the age of 12 within the last five years in order to be considered a pediatric reviewer on the Review Board.

The Pediatric Committee and NATCO also recommended monitoring the volume and outcomes of pediatric exceptions to support future development of policy and guidance. The Committee agreed and plans to convene the Review Board regularly to discuss concerns, monitor trends, and recommend actions to the Committee, including policy, guidance, and guideline changes.

Review Board Operations

Representatives

The Operations and Safety Committee (OSC) suggested identifying a percentage of lung transplant programs as reviewers rather than a set number so that the review board will remain representative of the community as the population of active lung transplant programs changes over time. The Transplant Coordinators Committee (TCC) suggested considering geographic location and program size when identifying review board representatives, as well as adult and pediatric lung transplant expertise. The Committee largely agreed with this feedback. When creating the cohorts for identifying Review Board representatives, the OPTN evaluated current waiting list registrations and divided lung transplant programs into three categories: small, medium and large. Transplant programs from each of these categories were divided into the five cohorts as evenly as possible. The OPTN also considered geographic location when dividing transplant programs into the cohorts. Because there are so few pediatric programs, they will be represented in the cohorts more often than other transplant programs. The Committee also retains the flexibility to add more lung transplant programs to the Review Board over time as needed.

Chair

Feedback was mixed as to whether the Review Board Chair should be a voting member of the review board. The American Society of Transplant Surgeons (ASTS) said the Chair does not need to be a voting member, whereas Region 7 said the Chair should be a voting member and AST agreed, noting that this would ensure a peer reviewed approach. Other comments said it seems reasonable for the Chair to vote unless there is a reason they should be recused, and the Operations and Safety Committee said whether the Chair should be a voting member should be consistent with other review boards.

The Committee decided that the Chair should not be a voting member so that the Chair's sole focus is to advise and support the review board members, rather than also having a responsibility to represent their transplant program on the review board. Accordingly, the Chair will not vote on any cases, but the OPTN will provide redacted clinical narratives to the Chair and the Lung Review Board Subcommittee in the months following implementation so that the Committee can provide guidance or clarifications as needed. Review Board members may also seek guidance from the Chair as needed to fulfill their duties.

Voting

Two comments said that a quorum of review board members should be required to approve or deny an exception request. ASTS recommended a quorum of five, and suggested that the Chair could cast a vote for reviews in which the minimum number of responses is not received in five days. AST suggested setting the quorum at greater than 50% of assigned reviewers or greater than five reviewers to ensure that one vote could not qualify as a majority. TCC recommended clarifying if a quorum is required. The Committee affirms that a quorum is not required, since reviewers tend to vote quickly and cases generally close prior to the end of the designated review timeframe. If the case is not closed out prior to the end of the five-day review period, then the voting section of the operational guidelines indicates how cases are decided based on the majority of votes submitted. In the unlikely scenario that a case is denied by a small number of reviewers, the transplant program would be able to appeal the case back to the Review Board, and again to the Committee, if need be.

ASTS expressed concern about the voting guidelines, specifically that reviewers who do not respond within three days would be replaced, and the review would be decided in five days even if there is only one response in that time frame. ASTS suggested that all nine transplant programs should have five days to respond, and after three days, the program's alternate representative would be approached. ASTS also expressed concern about when the countdown starts for the five day period and suggested sending out all cases in the morning of the first day so that representatives have three full days to respond. The Committee notes that the day that the request is assigned to reviewers is considered "day 0," so reviewers will have three full days after that to review the request. The Committee proposes retaining the framework in which a case would be assigned to another reviewer rather than to an alternate at the same transplant program in the event that the assigned reviewer did not respond within three days. The Committee also intends to retain the five-day review period in order to ensure cases are adjudicated quickly so as not to disadvantage a candidate in need of an exception. The Committee notes that most cases are closed within about two days in the current system, as shown in **Table 1**, and the new system will be more accessible to users since it will be implemented in the OPTN Computer System.

TCC recommended clarifying how alternate representatives with be notified, and another comment suggested notifying both the primary and alternate representatives on day 1 and if primary representative does not vote on day 3, then the alternate representative should be notified. The Committee notes that alternate representatives will be notified via email, and notifications will only be sent if action is required. If a reviewer does not vote within three days, the case will be assigned to another reviewer. This reviewer will not be the alternate at the same transplant program. The Committee notes that if alternates were to receive notifications on all cases, including many cases on which they will not be able to vote, then they may miss the occasions in which they do need to take action on a case.

Appeals

Several comments said that the appeals process is clear. Region 7 also supported the proposed policy change to shorten the timeline for the second appeal from 14 days to 7 days. Two comments said that the Committee should review appeals no later than 14 days after receiving the appeal so as not to

negatively impact patients. The Committee agreed and updated the policy language to indicate that the Committee will review appeals within 14 days, though in practice the Committee will aim to review appeals within seven calendar days. OSC recommended ensuring that the language regarding the appeals process is also understandable to patients. The OPTN will host a patient webinar on continuous distribution of lungs prior to implementation and will review the exceptions process as part of the webinar.

Other Feedback

One comment emphasized that patient education is important with implementation of the new guidelines. NATCO also recommended providing training for lung transplant programs and review board members. In September 2022, the OPTN released a training entitled "Scoring and Exceptions Under Lung Continuous Distribution,"[22] and the OPTN is developing a new training for Review Board members. The OPTN is also developing materials for patients regarding implementation of continuous distribution of lungs and updates will be posted on the lung continuous distribution policy toolkit.[23]

Another comment said that the OPTN should further refine the online portal. Implementation of this proposal includes shifting the review board process into the OPTN Computer System, with several updates to the online user experience. AST said that the OPTN should also provide information about candidates that are currently listed to support transplant programs in submitting a fair score request. In September 2022, the OPTN released a program-specific composite allocation score (CAS) resource report in the Data Services Portal in the OPTN Computer System. Additionally, the OPTN published a set of CAS summary reference statistics so that transplant programs can see how the calculated CAS for their currently registered candidates compare to the broader lung candidate population.[24] The OPTN will also provide monthly updates on the national distribution of the waiting list survival and post-transplant outcomes scores to aid members in submitting exception requests, similar to what is currently provided for LAS.[25]

AST suggested providing clinical guidance on exceptions for candidates with concomitant lung disease, such as combined pulmonary fibrosis and emphysema, and obstructive sleep apnea. The Lung Review Board Subcommittee will consider whether to provide additional clinical guidance when they begin to meet.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule, and to support the operation of the OPTN.[26] NOTA requires the OPTN to "establish…medical criteria for allocating organs and provide to members of

[22] Training is available in the OPTN Learning Management System, UNOS Connect: https://unos.org/resources/education/
[23] "Lung continuous distribution policy," OPTN, accessed November 1, 2022, https://optn.transplant.hrsa.gov/professionals/by-organ/heart-lung/lung-continuous-distribution-policy/.
[24] "Lung CAS Summary," UNOS, September 27, 2022, accessed October 8, 2022, https://unos.org/news/lung-cas-score-summary/.
[25] "Submitting LAS exception requests for candidates diagnosed with PH," UNOS, accessed June 14, 2022, https://unos.org/news/submitting-las-exception-requests-for-candidates-diagnosed-with-ph/.
[26] 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.

the public an opportunity to comment with respect to such criteria."[27] The medical criteria for allocating lungs were established in the proposal to *Establish Continuous Distribution of Lungs*.[28]

The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including "reducing inter-transplant program variance."[29] This proposal provides guidance for transplant programs on submitting exception requests if the transplant program believes that the medical criteria used in lung allocation do not provide appropriate access to transplant for a candidate, and will also assist in reducing inter-transplant program variance by facilitating more consistent review of exception cases.

The OPTN Final Rule states that the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[30] Such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."[31] This proposal:

- **Is based on sound medical judgment**[32] because it provides guidance on submitting exception requests that are supported by established clinical evidence, particularly for candidates with pulmonary hypertension. Changes to review board policies are also based on OPTN data and experience of past OPTN review board members.
- **Seeks to achieve the best use of donated organs**[33] by ensuring organs are allocated and transplanted according to medical urgency (based on estimated waiting list survival). The proposal provides guidance for requesting exceptions for this component of the lung composite allocation score so that candidates are appropriately prioritized for access to donated organs.
- **Is designed to…promote patient access to transplantation**[34] by giving similarly situated candidates equitable opportunities to receive an organ offer. Transplant programs may submit exception requests with clinical evidence indicating that their candidates are more similarly situated to candidates with higher allocation scores.
- **Is not based on the candidate's place of residence or place of listing.**[35] Transplant programs may not request an exception score for the placement efficiency component of the lung composite allocation score. This score is calculated at the time of the match run, based on the location of the donor. As stated above, since this component is not based solely on a candidate characteristic and does not stay stable, the Committee did not anticipate a current justification for a placement efficiency exception that would apply to all matches with that candidate.

[27] 42 USC §274(b)(2)(B)
[28] "Establish Continuous Distribution of Lungs," OPTN, Notice of OPTN Policy Changes, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.
[29] 42 CFR §121.8(b)(4)
[30] 42 CFR §121.4(a)(1)
[31] 42 CFR §121.8(a)
[32] 42 CFR §121.8(a)(1)
[33] 42 CFR §121.8(a)(2)
[34] Id.
[35] 42 CFR §121.8(a)(8)

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[36] and it is specific to an organ type, in this case lung.[37]

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

- Designed to avoid wasting organs[38]
- Designed to avoid futile transplants[39]
- Promotes the efficient management of organ placement[40]

Transition Plan

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.[41] The Committee did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies" if these proposed policy changes are approved by the Board of Directors, because the policy changes are largely administrative in nature and do not impact any particular subgroup of lung candidates.

With the implementation of continuous distribution of lungs, any exceptions held for candidates based on the current allocation system will no longer be in effect. Prior to implementation, transplant programs will have the opportunity to submit exception requests for their candidates based on their lung CAS. Since the lung CAS accounts for factors not included in LAS, like blood type, CPRA, and height, it is possible that candidates who hold LAS exceptions will not need or will not be approved for lung CAS exceptions. As outlined in the proposed guidance, transplant programs must provide clinical justification for exception requests.

OPTN Strategic Plan

This proposal aligns with the strategic plan goal to improve equity in access to transplants by allowing candidates to request a score more in line with their actual waiting list urgency, projected post-transplant mortality, biology, or other characteristics that impact patient access. This proposal will also improve the reliability of decisions about whether an exception is warranted by standardizing the process and making it as transparent as possible.

Implementation Considerations

Transplant hospitals that perform lung transplants and the OPTN would need to take action to implement this proposal. This proposal is not anticipated to affect the operations of organ procurement organizations or histocompatibility laboratories.

Transplant Programs

Operational Considerations

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[36] 42 CFR §121.8(a)(3)
[37] 42 CFR §121.8(a)(4)
[38] 42 CFR §121.8(a)(5)
[39] Id.
[40] Id.
[41] 42 CFR § 121.8(d)

Transplant hospitals with active lung transplant programs will be able to appoint review board representatives to the new Review Board on a regular basis. All lung transplant programs will not have representatives on the review board at all times. Appointed representatives will be expected to actively participate in the review board by voting on assigned cases within three days following case assignment. Prior to implementation, lung transplant programs will need to review their candidates, particularly those who hold approved LAS exceptions, to determine if they should submit any lung CAS exception requests.

Fiscal Impact

Review board members and transplant hospitals with lung transplant programs will want to familiarize themselves with the review board changes and educate staff on changes to exceptions.

OPTN

Operational Considerations

These changes would be used to implement the review board for requests for exceptions to the components of the lung CAS. The review board would begin work about a month before the CAS allocation changes take effect, in order to ensure that any needed exceptions can be awarded before the new scores impact allocation of lungs.

Resource Estimates

The OPTN contractor estimates 495 hours for implementation. Implementation will involve updates to the OPTN website, education and training on the changes, and communications efforts about the changes. The OPTN contractor estimates 110 hours for ongoing support. Ongoing support will involve answering member questions and monitoring of exceptions at 3 months, 6 months, and then annually for 3 years following the allocation change.

Post-implementation Monitoring

Member Compliance

This proposal will not change current routine monitoring of OPTN members.

Policy Evaluation

As delineated in the proposal to *Establish Continuous Distribution of Lungs*,[42] the OPTN will monitor exceptions. Specifically, metrics to be evaluated include**:**

Waiting List

- Number of exception requests, overall and by diagnosis group

Transplants

- Number of transplant recipients with an exception request, overall and by diagnosis group.

[42] "Establish Continuous Distribution of Lungs," OPTN, Notice of OPTN Policy Changes, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

Monitoring reports using pre vs. post comparisons will be presented to the Committee approximately 3 months, 6 months, and then annually for 3 years following the allocation change.

Conclusion

In support of the pending implementation of continuous distribution of lungs, this proposal would establish operational guidelines that outline representation, responsibilities, and process for the Lung Review Board; clinical guidance on exception requests for transplant programs and review board members; and policy changes to align OPTN resources on the Lung Review Board with those of other organs. In response to public comment feedback, this proposal was updated to strengthen pediatric representation on the Lung Review Board, provide guidance on pediatric exceptions, and ensure the Committee responds expediently to appealed exception requests.

Policy, Guidance and Guidelines Language

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

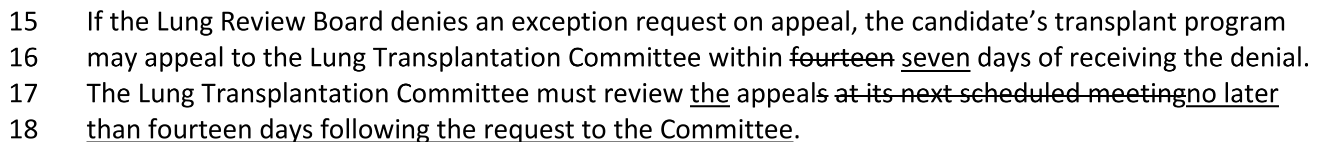
10.2.C Review of Exceptions

The Lung Review Board must review exception requests within five days of the date the request is submitted to the Lung Review Board. ~~If the Lung Review Board fails to make a decision on the initial exception request by the end of the five-day review period, the candidate will be assigned the requested exception score.~~

10.2.D Appeals to Lung Review Board

If the Lung Review Board denies an exception request, the candidate's transplant program may appeal to the Lung Review Board within seven days of receiving the denial. The Lung Review Board must review appeals within five days of the date the appeal is submitted to the ~~OPTN~~ Lung Review Board. ~~If the Lung Review Board fails to make a decision on the appeal by the end of the five-day appeal period, the candidate will be assigned the requested exception score.~~

10.2.E Appeals to Lung Transplantation Committee



If the Lung Review Board denies an exception request on appeal, the candidate's transplant program may appeal to the Lung Transplantation Committee within ~~fourteen~~ seven days of receiving the denial. The Lung Transplantation Committee must review the appeal~~s at its next scheduled meeting~~no later than fourteen days following the request to the Committee.

19 # Lung Review Board Guidance

20 ## Summary and Goals

21 Policy 10.2 allows a transplant program to submit exception requests for Medical Urgency, Post-
22 Transplant Outcomes, Biological Disadvantages, and/or Patient Access Scores. The Lung Review Board
23 (Review Board) provides prompt peer review of candidate score exceptions on the lung transplant
24 waiting list. These guidelines are intended to promote consistent review of these scores.

25 When submitting an exception request, transplant programs must provide a clinical justification for the
26 exception. Please refer to *Policy 10.2 Lung Composite Score Exceptions* for additional information about
27 the exception review process.

28 This resource is not OPTN Policy, so it does not carry the monitoring or enforcement implications of
29 policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or
30 to define a standard of care. This resource is intended to provide guidance to transplant programs and
31 the Review Board.

32 ## Recommendations

33 ### Exception Requests

34 In addition to the requirements listed in *OPTN Policy 10.2.B Exception Requests*, requesting transplant
35 programs are encouraged to include citations to supporting literature where available. Transplant
36 programs are encouraged to consult the CAS calculator, and the national score distribution information
37 when considering what score to request, and may wish to include information in the request about how
38 these were used in the choice of a requested score.

39 *Pulmonary Hypertension*

40 Lung transplant candidates diagnosed with pulmonary hypertension (PH) and who meet the following
41 criteria may qualify for an increase in their Waitlist Survival and/or Post-Transplant Outcomes Scores:

42 1. Patient is deteriorating on optimal therapy, and
43 2. Patient has a right atrial pressure greater than 15 mm Hg *or* a cardiac index less than 1.8
44 $L/min/m^2$.

45 To request an increase in a PH candidate's scores, transplant programs must submit an exception
46 request to the Review Board; this request should include sufficient clinical detail to support that the
47 patient meets the above criteria.

48 If the transplant program believes that its patient has similar waiting list mortality and potential
49 transplant benefit as a PH patient meeting the criteria listed above, then it should provide a detailed
50 narrative on that assertion, referencing literature supporting the request for a higher score.

51 Transplant programs may wish to submit to the Review Board exception requests for the candidate's
52 Waitlist Survival Score and Post-Transplant Outcomes Score to be at the national 90th percentile for each
53 goal. This information is provided by the OPTN on a rolling basis.

54 *Pediatric Priority 1*

55 To request a pediatric priority 1 exception for a candidate currently assigned to priority 2, transplant
56 programs should request an exception for 7.6292% of the waitlist survival score to get the 1.9073
57 waitlist points assigned to pediatric priority 1 candidates. It is not necessary to request an exception for
58 post-transplant outcomes since pediatric priority 1 and 2 candidates are assigned the same number of
59 post-transplant outcomes points.

Lung Review Board Operational Guidelines[43]

1 Repealed.

2 Lung Review Board Operational Guidelines

3 Overview

4 The purpose of the Lung Review Board (Review Board) is to provide fair, equitable, and prompt peer
5 review of exception requests. The Review Board will review these exception requests and determine if
6 the request is comparable to other candidates with the same score.

7 Representation

8 *Policy 10.2 Lung Composite Score Exceptions* sets the structure and composition of the Review Board.

9 The membership of the Review Board is comprised of representatives from active lung transplant
10 programs. Review Board members serve a term of 2 years. Service terms will be staggered among the
11 Review Board members with a portion of active lung transplant programs permitted to appoint
12 representatives each term. The Review Board membership is rotated to ensure each transplant program
13 has equal opportunity to participate. Each participating lung transplant program may appoint a primary
14 and an alternate representative. At least 4 of the active lung transplant programs must have performed
15 at least one transplant for a candidate under the age of 12 within the last five years. The Review Board
16 members from lung transplant programs that have performed at least one transplant for a candidate
17 under the age of 12 within the last five years will be given priority for assignment to pediatric cases if
18 they are available.

19 The immediate past Chair of the Lung Transplantation Committee will serve as the Review Board Chair
20 for a 2-year term. In the event of a Review Board Chair vacancy, the Lung Transplantation Committee
21 Chair will appoint a Review Board Chair.

22 Qualifications to serve on the Review Board include:
23 - The Review Board representative must be employed at an active lung transplant program.
24   - If a transplant hospital inactivates or withdraws its lung program, the Review Board
25   representative from that hospital may not participate in the Review Board.
26   - If a transplant hospital inactivates or withdraws its pediatric lung component, the
27   Review Board representative from that hospital may not participate in the Review
28   Board.
29   - The term of the transplant program or component's representative on the Review Board
30   ends upon program or component's inactivation or withdrawal from the OPTN. Should a
31   transplant program reactivate, it may again have the opportunity to be represented on
32   the Review Board during future rotations.
33   - It is the responsibility of each transplant program to provide the OPTN Contractor with
34   the contact information for the both the primary Review Board representative and the
35   alternate from their program. Should a representative leave his transplant program,

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[43] "Lung Review Board Information," OPTN, January 2015, accessed June 23, 2022, https://optn.transplant.hrsa.gov/media/2701/review_board_guidelines_lung.pdf.

36 then the program's alternate representative will become the primary Review Board
37 member. The departing member will be removed from the Review Board.
38 • Complete a conflict of interest and confidentiality statement and orientation training prior to
39 each term of service.
40 • The primary representative must have at least five years of post-training transplant experience.
41 • The alternate representative must have at least three years of post-training transplant
42 experience.
43 • Transplant programs must ensure that Review Board volunteers from their programs meet
44 these requirements.

45 Chair Responsibilities

46 The Review Board Chair:
47 A. Serves as a liaison between the Review Board and the Lung Transplantation Committee.
48 B. May remove members of the Review Board who the Chair identifies as non-responsive to
49 Review Board cases.

50 Representatives Responsibilities

51 Review Board representatives must:
52 A. Vote on all exception requests and appeals according to the timelines set by policy.
53 B. When voting to deny an exception, provide constructive comments that are relevant to the
54 candidate's clinical information and based on policy or guidance documents. These comments
55 will be provided to the candidate's lung program.
56 C. Notify the OPTN of any planned absences. Requests will not be assigned to representatives who
57 indicate they are out of the office.

58 The alternate representative will only be assigned cases if the primary representative indicates they are
59 out of the office.

60 Voting Procedure

61 The OPTN Contractor will send the exception request or appeal to nine of the Review Board members. If
62 there are fewer than nine reviewers available, the OPTN Contractor will send the case to all available
63 reviewers.

64 If the assigned Review Board member has not voted within three days of when the OPTN Contractor
65 sends the application or appeal to the Review Board, then the request will be reassigned to another
66 representative.

67 The Review Board will review all exception requests prospectively. The candidate will not receive the
68 exception score unless or until it is approved.

69 Voting will close at the earliest of when:
70 • A majority of all assigned voters have voted to approve an exception request
71 • A majority of all assigned voters have voted to deny an exception request
72 • The timeline lapses for the Review Board members to vote on the exception request.
73 The Review Board will have five days to vote and exception requests will be decided as follows:
74

Of the votes submitted, if…	The request is…
The majority vote to approve	Approved
The majority vote to deny	Denied
There is a tie	Approved
No votes are submitted	Approved

75 A majority is more than half of the votes submitted.

76 Appeal Process

77 A candidate's lung program may appeal the Review Board's decision to deny an exception request
78 within seven days of receiving the appeal denial notification. All representative comments of denied
79 requests are provided to the lung program. The program must submit additional written information
80 justifying or amending the requested exception and may include responses to the comments of
81 dissenting Review Board representatives. This additional information will be provided to the Review
82 Board representatives for further consideration. To the extent possible, the appeal will be considered by
83 the same reviewers who considered the initial exception application. Exception requests appealed to the
84 Review Board are adjudicated as described in Voting Procedure, above.

85 Following a denial on an appeal to the Review Board, the candidate's lung program can appeal to the
86 Committee. The lung program must appeal within 7 days of notification. The program can provide
87 additional written information justifying or amending the requested exception to be sent to the
88 Committee. The Committee will approve or deny each appeal no later than fourteen days following the
89 request to the Committee. Exception requests appealed to the Committee are adjudicated as follows:

Of the votes submitted, if…	The request is…
The majority vote to approve	Approved
The majority vote to deny	Denied
There is a tie	Approved

90 Any member of the Committee who reviewed the case as a Review Board representative must abstain
91 from voting on the appeal to the Committee.

#