

Public Comment Proposal

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

OPTN Lung Transplantation Committee

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

<i>Affected Policies:</i>	<i>10.2.C: Review of Exceptions</i> <i>10.2.D: Appeals to Lung Review Board</i> <i>10.2.E: Appeals to Lung Transplantation Committee</i>
<i>Sponsoring Committee:</i>	<i>Lung Transplantation</i>
<i>Public Comment Period:</i>	<i>August 3, 2022 – September 28, 2022</i>

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 established a Lung Review Board to evaluate requests for exceptions to components of 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 to components of their lung composite allocation score. It would also establish clinical guidelines for transplant programs who wish to submit an exception request, and for Lung Review Board members when reviewing 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. The intent is to put in place an exception review framework that is consistent across organs and candidates. This proposal would also make minor policy changes to improve consistency across organs in terms of where members can find information on review boards between 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

The Board of Directors approved significant lung allocation changes in December 2021, with the passage of *Establish Continuous Distribution of Lungs*.² That change established a Lung Review Board to evaluate requests for exceptions to components of the new lung composite allocation score (CAS). In order to ensure as consistent a review as possible, the OPTN Lung Transplantation Committee (Committee) proposes the adoption of:

1. Operational guidelines that outline representation, responsibilities, and process for the 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 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 *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 by policy. The Lung Review Board reviews the exception requests and either denies or approves them. Requirements and processes for the Lung Review Board are delineated in OPTN Policies and in operational guidelines.³

The Board of Directors approved significant lung allocation changes in December 2021, with the passage of *Establish Continuous Distribution of Lungs*.⁴ 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. Accordingly, the approved policy changes also established a Lung Review Board to evaluate requests for exceptions to components of the lung CAS. The Committee requested feedback on the composition and function of the Lung Review Board as part of the public comment proposal for continuous distribution,⁵ and this proposal incorporates that feedback.⁶

Similar to the current system, the new Lung 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

² "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.

³ "Lung Review Board Information," OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/2701/review_board_guidelines_lung.pdf.

⁴ "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.

⁵ "Establish Continuous Distribution of Lungs," OPTN, Public Comment Proposal, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/4772/continuous_distribution_of_lungs-public_comment.pdf.

⁶ "Establish Continuous Distribution of Lungs," OPTN, Public Comment Web Page, accessed June 12, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-continuous-distribution-of-lungs/>.

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.⁷ Exceptions will be reviewed prospectively by the Lung Review Board, and exceptions will not expire.

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

Overview of Proposal

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

Operational Guidelines: Review Board Composition

Reviewer Rotation and Representation

The current Lung Review Board is comprised of nine individual lung transplant surgeons or physicians. The Committee proposes having representatives from twelve transplant programs on the new Lung Review Board, with each of the twelve transplant programs appointing a primary review board member and an alternate. Nine reviewers would be assigned to each exception request.

Other organ-specific national review boards allow each active transplant program for the organ an opportunity 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 representing all lung transplant programs on the review board at all times. Each year, approximately 1/5 of the active lung transplant programs would have an opportunity to appoint a review board member and alternate to the Lung 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	Year 6
1 st Cohort						
2 nd Cohort						
3 rd Cohort						
4 th Cohort						
5 th 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

⁷ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed June 14, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

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 other changes in the future. It also ensures that a rotation is maintained, even if such changes are needed.

There are currently 71 active lung programs. 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 to 30 transplant programs eligible to have representatives on the Lung Review Board at any point in time. Each year, OPTN staff will reach out to the programs in the designated cohorts to request volunteers to serve on the Lung Review Board, and will accept as many volunteers 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.⁸ Transplant programs should ensure that Lung Review Board volunteers from their programs meet these requirements when submitting volunteers.

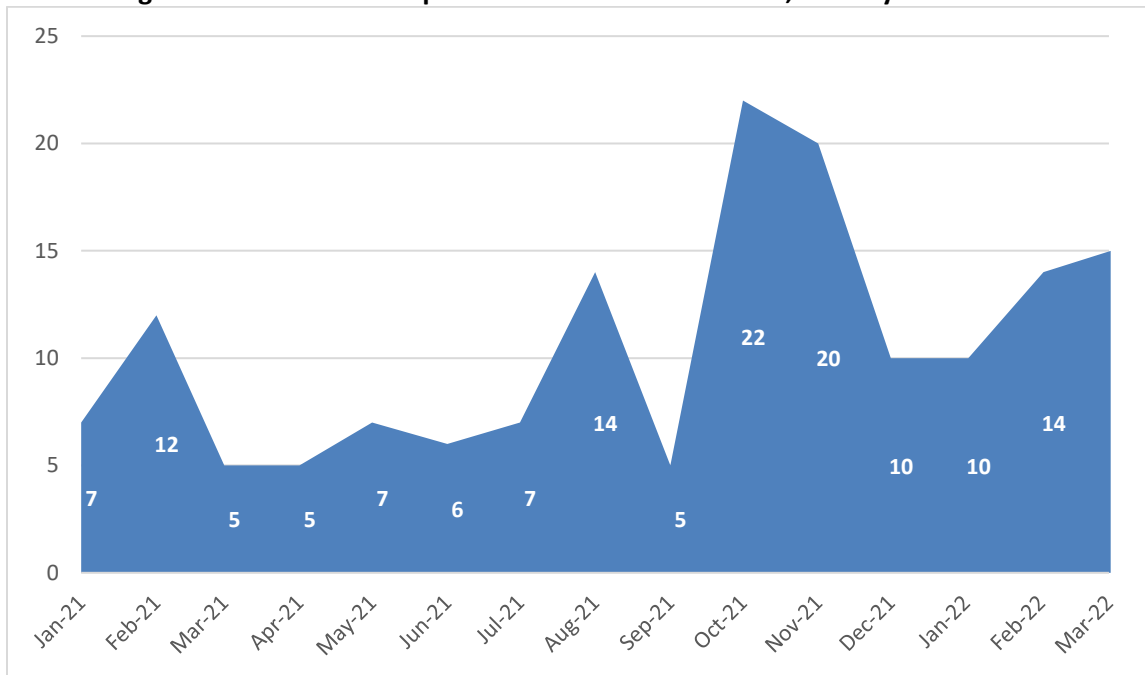
The lower requirement for alternate representatives is intended to allow those with less experience an opportunity to serve on the review board and learn. The alternates are less likely to be appointed to an exception case, since primary review board members will be assigned to cases first, and it is even more unlikely that multiple alternates will be assigned the same exception request. 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 Lung Review Board members currently serving would be assigned to the case. The Committee considered the appropriate number of reviewers to assign to each 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 Lung 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**.

⁸ 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.

Figure 2: Number of Exceptions Submitted Each Month, January 2021 – March 2022⁹



Historically, there have been between 5 and 22 lung exception cases each month, as shown above. The Committee proposes assigning nine reviewers to each exception request. For each exception case, nine of the active reviewers for that year would be randomly selected to review that case. 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. This change would allow for system efficiencies in implementation, and more consistency in review board operations across organs. It is more similar to the liver¹⁰ and pediatric heart review boards,¹¹ which have larger review boards and assign cases to a smaller subset of review board members.

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.¹² However, there are not sufficient pediatric lung transplant programs to ensure that only those with pediatric experience will review pediatric cases. Additionally, the Committee believes there is value in including adult experts with pediatric experts in the review of pediatric exception requests to ensure that such reviews are balanced in light of priority compared to candidates of all ages.

⁹ OPTN, Lung Review Board, HRSA Quarterly Reports, January 2021 – April 2022.

¹⁰ “National Liver Review Board Operational Guidelines,” OPTN, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/ywxddona/20200804_nlr_operational_guidelines.pdf.

¹¹ “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.

¹² 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.

The Committee proposes ensuring that at least three pediatric programs are represented on the review board at any given time. There are 36 transplant programs that have active pediatric programs and nine programs with pediatric candidates currently listed.¹³ The proposed five-year rotation would ensure this minimum is reached. The Review Board members from pediatric programs would be given priority for assignment to pediatric cases as long as they have not reported that they are out of the office.

Chair

The Committee proposes including a chairperson for the Lung Review Board. This position will be modeled after the National Liver Review Board chair,¹⁴ 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.

The chair is proposed to be a normal voting member, participating in the review process in the same way as any other review board member. The chair would not have the ability to break ties or have any other increased voting rights beyond those given to the other review board members. However, the chair is expected to serve as a liaison between the Review Board and the Committee. For example, the chair can notify the Committee of themes in exception requests that may warrant consideration for adoption in policy.

Operational Guidelines: Voting

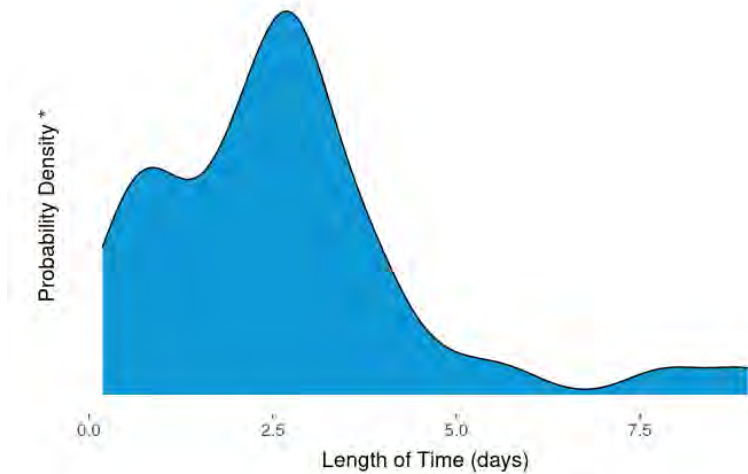
A five-day time frame for review of all exception cases was established with a policy change in the proposal to *Establish Continuous Distribution of Lungs* approved in December 2021.¹⁵ As shown in **Figure 3**, most exception cases are processed within five days. The Committee does not propose changing that timeframe here, but proposes to move the timeframe requirement from policy into the operational guidelines to streamline the language and avoid duplicating language. This will help with maintaining the language if future changes are made.

¹³ OPTN data as of June 13, 2022.

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

¹⁵ "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.

Figure 3: Distribution of Lung Review Board Process Times for Exceptions Requested January 1, 2022 – March 31, 2022¹⁶



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 other review board members 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 Lung 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 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.¹⁷

If the majority of votes submitted vote not to approve 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**, 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 decided an outcome on an exception request, the case could be appealed back to the broader Review Board, and again to the Committee.

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

¹⁶ 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.

¹⁷ "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/>.

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 sent again to the same group of reviewers who initially denied the exception request. This would allow the transplant program to respond with regard 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 consider the appeal by the next scheduled Committee meeting.

Clinical Guidance

The Committee proposes guidance for transplant programs around what types of information to include in 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).¹⁸ 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/m²).¹⁹ 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.

Policy Changes

The approved policy changes for the Lung Review Board stated that if the Lung 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.²⁰

Additionally, the Committee proposes that if the Lung 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

¹⁸ "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.

¹⁹ "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/>.

²⁰ "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.

timeline for appealing exception requests to the Lung 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*.

NOTA and Final Rule Analysis

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.²¹ NOTA requires the OPTN to “establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria.”²² The medical criteria for allocating lungs were established in the proposal to *Establish Continuous Distribution of Lungs*.²³

The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including “reducing inter-transplant program variance.”²⁴ 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.”²⁵ 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.”²⁶ This proposal:

- **Is based on sound medical judgment**²⁷ 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**²⁸ 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**²⁹ by giving similarly situated candidates equitable opportunities to receive an organ offer. Transplant programs may submit

²¹ 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.

²² 42 USC §274(b)(2)(B)

²³ “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.

²⁴ 42 CFR §121.8(b)(4)

²⁵ 42 CFR §121.4(a)(1)

²⁶ 42 CFR §121.8(a)

²⁷ 42 CFR §121.8(a)(1)

²⁸ 42 CFR §121.8(a)(2)

²⁹ Id.

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.**³⁰ 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.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,³¹ and it is specific to an organ type, in this case lung.³²

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 organs³³
- Designed to avoid futile transplants³⁴
- Promotes the efficient management of organ placement³⁵

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.³⁶ 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.

Implementation Considerations

Member and OPTN Operations

This proposal is expected to have an operational impact on transplant hospitals and the OPTN but is not expected to have any impact on organ procurement organizations or histocompatibility laboratories.

Transplant Hospitals Operational Impact

Transplant hospitals with active lung transplant programs will be able to appoint review board representatives to the new Lung 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 of case assignment.

³⁰ 42 CFR §121.8(a)(8)

³¹ 42 CFR §121.8(a)(3)

³² 42 CFR §121.8(a)(4)

³³ 42 CFR §121.8(a)(5)

³⁴ Id.

³⁵ Id.

³⁶ 42 CFR § 121.8(d)

OPTN Operational Impact

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.

Potential Impact on Select Patient Populations

This proposal allows transplant programs to request higher allocation scores for their patients based on clinical evidence to ensure that patients have the appropriate access to transplant. The proposal is also intended to provide some standardization for reviewing such requests so that exceptions are granted in a fair and consistent manner. The proposal provides specific recommendations for requesting exceptions for candidates with pulmonary hypertension, since there is clinical consensus that the estimated waitlist survival and post-transplant outcomes components of the lung CAS may not fully reflect increased mortality associated with an acute progression of pulmonary hypertension.³⁷

Projected Fiscal Impact

This proposal is expected to have a small fiscal impact on transplant hospitals and the OPTN but is not expected to have any impact on organ procurement organizations or histocompatibility laboratories.

Projected Impact on Transplant Hospitals

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.

Projected Impact on the OPTN

The OPTN supported Committee meetings as well as drafting, review, and revisions of policy, guidance, and operational guidelines. The proposed changes would not require additional implementation in the OPTN Computer System but would require updates to the OPTN website, educational offerings for lung transplant programs, and continued monitoring of exception requests for lung candidates.

Post-implementation Monitoring

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”³⁸ Additionally, the Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”³⁹ The member compliance and policy evaluation plans are detailed below.

Member Compliance

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

³⁷ “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.

³⁸ 42 CFR §121.8(a)(7)

³⁹ 42 CFR §121.8(a)(6)

Policy Evaluation

As delineated in the proposal to *Establish Continuous Distribution of Lungs*,⁴⁰ 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.

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 review board; clinical guidance on exception requests for transplant programs and review board members; and minor policy changes to align OPTN resources on the Lung Review Board with those of other organs.

Considerations for the Community

The Committee requests feedback on the following questions:

- Should the Committee add information in the guidance on how to request a priority 1 equivalent score for pediatric candidates in the new allocation system?
- Should the Chair be a voting member of the Lung Review Board?
- Are there other specific candidate diagnoses, symptoms, or characteristics for which the Committee should consider providing more specific guidance?
- Should a quorum of review board members be required to deny an exception request?
- Is it clear how the appeals process works?
- Do lung transplant programs anticipate any barriers to participating in the new Lung Review Board or using the updated exceptions process?
- What resources should the OPTN provide to assist lung transplant programs in submitting exception requests in the continuous distribution lung allocation system?

⁴⁰ "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.

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.

1 **10.2.C Review of Exceptions**

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

7 **10.2.D Appeals to Lung Review Board**

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

14 **10.2.E Appeals to Lung Transplantation Committee**

15 If the Lung Review Board denies an exception request on appeal, the candidate’s transplant
16 program may appeal to the Lung Transplantation Committee within ~~fourteen~~ seven days of
17 receiving the denial. The Lung Transplantation Committee must review appeals at its next
18 scheduled meeting.

19

20 Lung Review Board Guidance

21 Summary and Goals

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

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

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

33 Recommendations

34 Exception Requests

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

40 *Pulmonary Hypertension*

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

- 43 1. Patient is deteriorating on optimal therapy, and
- 44 2. Patient has a right atrial pressure greater than 15 mm Hg or a cardiac index less than 1.8
45 L/min/m².

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

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

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

Lung Review Board Operational Guidelines⁴¹

55 Repealed.

56 Lung Review Board Operational Guidelines

57 Overview

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

61 Representation

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

63 The membership of the Review Board is comprised of representatives from active lung transplant
 64 programs. Review Board members serve a term of 2 years. Service terms will be staggered among the
 65 Review Board members with a portion of active lung transplant programs permitted to appoint
 66 representatives each term. The Review Board membership is rotated to ensure each transplant program
 67 has equal opportunity to participate. Each participating lung transplant program may appoint a primary
 68 and an alternate representative. At least 3 active pediatric lung transplant programs are represented on
 69 each term. The Review Board members from pediatric lung transplant programs will be given priority for
 70 assignment to pediatric cases if they are available.

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

74 Qualifications to serve on the Review Board include:

- 75 • The Review Board representative must be employed at an active lung transplant program.
 - 76 ○ If a transplant hospital inactivates or withdraws its lung program, the Review Board
 - 77 representative from that hospital may not participate in the Review Board.
 - 78 ○ If a transplant hospital inactivates or withdraws its pediatric lung component, the
 - 79 Review Board representative from that hospital may not participate in the Review
 - 80 Board.
 - 81 ○ The term of the transplant program or component's representative on the Review Board
 - 82 ends upon program or component's inactivation or withdrawal from the OPTN. Should a
 - 83 transplant program reactivate, it may again have the opportunity to be represented on
 - 84 the Review Board during future rotations.
 - 85 ○ It is the responsibility of each transplant program to provide the OPTN Contractor with
 - 86 the contact information for the both the primary Review Board representative and the
 - 87 alternate from their program. Should a representative leave his transplant program,
 - 88 then the program's alternate representative will become the primary Review Board
 - 89 member. The departing member will be removed from the Review Board.
- 90 • Complete a conflict of interest and confidentiality statement and orientation training prior to
- 91 each term of service.

⁴¹ "Lung Review Board Information," OPTN, January 2015, accessed June 23, 2022, https://optn.transplant.hrsa.gov/media/2701/review_board_guidelines_lung.pdf.

- The primary representative must have at least five years of post-training transplant experience.
- The alternate representative must have at least three years of post-training transplant experience.

Chair Responsibilities

The Review Board Chair:

- A. Participates as a voting member of the Review Board.
- B. Serves as a liaison between the Review Board and the Lung Transplantation Committee.
- C. May remove members of the Review Board who the chair identifies as non-responsive to Review Board cases.

Representatives Responsibilities

Review Board representatives must:

- A. Vote on all exception requests and appeals according to the timelines set by policy.
- B. When voting not to approve an exception, provide constructive comments that are relevant to the candidate's clinical information and based on policy or guidance documents. These comments will be provided to the candidate's lung program.
- C. Notify the OPTN of any planned absences. Requests will not be assigned to representatives who are known to be unavailable to review requests.

Voting Procedure

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

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

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

Voting will close at the earliest of when:

- A majority of all eligible voters have voted to approve an exception request
- A majority of all eligible voters have voted not to approve an exception request
- The timeline lapses for the Review Board members to vote on the exception request.

The Review Board will have five days to vote and exception requests will be decided as follows:

<u>Of the votes submitted, if...</u>	<u>The request is...</u>
<u>The majority vote to approve</u>	<u>Approved</u>
<u>The majority vote to not approve</u>	<u>Denied</u>
<u>There is a tie</u>	<u>Approved</u>
<u>No votes are submitted</u>	<u>Approved</u>

A majority is more than half of the votes submitted.

125 **Appeal Process**

126 A candidate's lung program may appeal the Review Board's decision to deny an exception request
127 within seven days of receiving the appeal denial notification. All representative comments of denied
128 requests are provided to the lung program. The program must submit additional written information
129 justifying or amending the requested exception and may include responses to the comments of
130 dissenting Review Board representatives. This additional information will be provided to the Review
131 Board representatives for further consideration. To the extent possible, the appeal will be considered by
132 the same reviewers who considered the initial exception application.

133 Following a denial on an appeal to the Review Board, the candidate's lung program can appeal to the
134 Committee. The lung program must appeal within 7 days of notification. The program can provide
135 additional written information justifying the requested exception status to be sent to the Committee.
136 The Committee will approve or not approve each appeal no later than the next scheduled Committee
137 call following the request to the Committee.

138 Appealed applications are adjudicated as described in Voting Procedure, above.

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