



**Title:** National Heart Review Board for Pediatrics

**Sponsoring Committee:** Thoracic Organ Transplantation

## What is current policy and why change it?

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Currently, when a transplant physician lists a candidate at a high urgency status (Status 1A or Status 1B) who does not meet the criteria for that status, they must submit justification for this exception to the OPTN for review by a Regional Review Board (RRB). Due to recent pediatric heart allocation changes, there has been an increase in pediatric candidates listed at higher statuses by exception, but pediatric transplant programs tend to be under-represented on RRBs.

## What's the proposal?

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- **Create a National Heart Review Board (NHRB) for Pediatric Candidates**
  - Each active pediatric heart program would be able to appoint **one primary** and **one alternate** representative to serve one year terms
  - NHRB would review exception requests for **Status 1A** and **Status 1B** pediatric heart candidates
  - Requests would be assigned to **nine randomly selected representatives**
  - Decisions based on **majority vote** within three days
  - Denials can **appeal** to same group of reviewers
    - Additional denial can be appealed to workgroup made up of members of Thoracic Committee and Pediatric Committee with relevant expertise

## What's the anticipated impact of this change?

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- **What it's expected to do**
  - Improve quality and consistency in review of pediatric heart exceptions
  - Work towards ensuring more medically appropriate status listings for pediatric heart patients
- **What it won't do**
  - It will not change the way exception requests for adult heart patients are reviewed.

## Themes to consider

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- How to ensure broad/equal representation on the NHRB
- How appeals should work
- What statuses should be reviewed
- Plan for tiebreakers

## Terms you need to know

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- **Status:** An indication of the degree of medical urgency for patients awaiting heart transplants. Status 1A is most urgent.
- **Exception:** When a physician places a candidate at a higher status even though the candidate does not meet the standard criteria in policy to automatically qualify for the status.
- **Review Boards:** Peer review panels established to review all urgent status listings for liver and heart candidates. The review boards reviews justification forms submitted by each center documenting the severity of the candidate's illness and justifies the status at which the candidate is listed. Thoracic review boards review listings for heart candidates in Status 1A and special case heart candidates in Status 1B. These boards also consider appeals of cases initially turned down for a particular medical urgency status.
- [Click here to search the OPTN glossary](#)

*Public Comment Proposal*


# National Heart Review Board for Pediatric Candidates

*OPTN Thoracic Organ Transplantation Committee*

*Prepared by: Elizabeth Miller  
UNOS Policy and Community Relations Department*

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# National Heart Review Board for Pediatric Candidates

<i>Affected Policies:</i>	<i>6.4: Adult and Pediatric Status Exceptions</i> <i>6.4.A: Review Board and Committee Review of Status Exceptions</i> <i>6.4.A.i: Review Board Appeals</i> <i>6.4.A.ii: Committee Appeals</i>
<i>Affected Guidelines:</i>	<i>National Heart Review Board Operational Guidelines - Pediatric</i>
<i>Sponsoring Committee:</i>	<i>Thoracic Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>January 22, 2020 – March 24, 2020</i>

## Executive Summary

The number of Status 1A listings by exception has increased and the degree of increase has been mixed across OPTN regions since the implementation of changes to the criteria for Status 1A. This disparity is influenced by regionally-separated review boards, with varying levels of pediatric expertise.

This proposal would create a national heart review board (NHRB) for pediatric heart candidates. Under the NHRB, each Status 1A and Status 1B exception request would be randomly assigned to a group of specialists in pediatric heart transplant from across the country who would decide whether to approve the request. The goals are that the specialized expertise and the use of reviewers from across the country would:

1. Improve the stratification of Status 1A and Status 1B candidates by aligning the waiting list mortality rates for pediatric candidates with Status 1A and Status 1B by exceptions with those based on the standard criteria
2. Reduce the regional variance in volume of Status 1A and Status 1B exceptions.

## Purpose of the Proposal

The purpose is to improve quality and consistency in the evaluation of exceptions for heart candidates listed before their 18<sup>th</sup> birthday. Pediatric heart candidates can be listed as Status 1A, Status 1B, Status 2 or Inactive. By default, active pediatric candidates are Status 2 unless they qualify for the increased priority of Status 1A or Status 1B.<sup>1</sup> Since the pediatric heart Status 1A and Status 1B criteria were redefined in policy changes that took effect on March 22, 2016,<sup>2</sup> there has been an increase in the number of Status 1A by exception listings and the number of candidates transplanted with Status 1A exceptions. There has also been increased regional variance in the proportion of pediatric transplants for candidates listed as Status 1A by exception.<sup>3</sup>

The Organ Procurement and Transplantation Network (OPTN) Thoracic Organ Transplantation Committee (Thoracic Committee) and OPTN Pediatric Transplantation Committee (Pediatric Committee) believe that the fragmented operation of the different regional review boards (RRBs) and the fact that most of the reviewers on the RRBs are not specialists in pediatric transplantation contribute to the increase in Status 1A exceptions and the variability among the numbers of Status 1A exceptions between regions. This proposal would create a National Heart Review Board (NHRB) for pediatric candidates.<sup>4</sup>

The NHRB would be comprised of representatives from pediatric heart programs all over the country, with reviewers randomly assigned to review the exception requests. The use of reviewers who are specialists in pediatric heart transplantation would be aimed at increasing the quality of the evaluation of these exception requests. The national board would be used to minimize local differences and improve consistency.

## Background

The National Organ Transplant Act of 1984, as amended (NOTA) provides special status to pediatric transplant candidates. Under NOTA, the OPTN is required to adopt criteria, policies, and procedures that address the unique health care needs of individuals under the age of 18.<sup>5</sup> As part of its ongoing commitment to this population, the Board approved changes to pediatric heart allocation policy in 2014, with the primary goal of improving waiting list mortality rates for pediatric heart candidates. The Board sought to achieve this in part by redefining pediatric status 1A and 1B criteria to make sure that candidates of comparable levels of medical urgency are in the same statuses.<sup>6</sup>

After implementation of those changes, as part of its work to monitor their effectiveness, the Thoracic and Pediatric Committees reviewed an evaluation report in April 2018 (Report).<sup>7</sup> Findings in the Report

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<sup>1</sup> OPTN Policy 6.2 Pediatric Status Assignments and Update Requirements

<sup>2</sup> Important Policy Notice, *Changes to the OPTN Policies and Bylaws from the June Board of Directors Meeting*, July 2014, [https://optn.transplant.hrsa.gov/media/1822/optn\\_policy\\_notice\\_07-24-2014.pdf](https://optn.transplant.hrsa.gov/media/1822/optn_policy_notice_07-24-2014.pdf) (accessed November 25, 2019).

<sup>3</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

<sup>4</sup> For purposes of this paper, pediatric candidates refers to candidates registered for a heart transplant before their 18<sup>th</sup> birthday.

<sup>5</sup> 42 U.S.C. 274(m).

<sup>6</sup> Briefing Paper, *Proposal to Change Pediatric Heart Allocation Policy*, Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee, April 2014.

<sup>7</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

raised concerns that the policy changes were having an inequitable effect on candidate access to organs and there were still different levels of medical urgency within each status. The Report showed an increased number of Status 1A exceptions.<sup>8</sup> The Status 1A candidates who were awarded Status 1A by exception had lower waiting list mortality than those who were placed at Status 1A by meeting the policy criteria, suggesting that some candidates who are not as medically urgent may be receiving the higher priority.<sup>9</sup> This results in a situation where the patients with the highest waiting list mortality could have decreased access to deceased donor hearts because deceased donor hearts are allocated to Status 1A exception patients who were not as medically urgent. This might be contributing to the lack of improvement in waiting list mortality rates overall following implementation of the new status criteria.

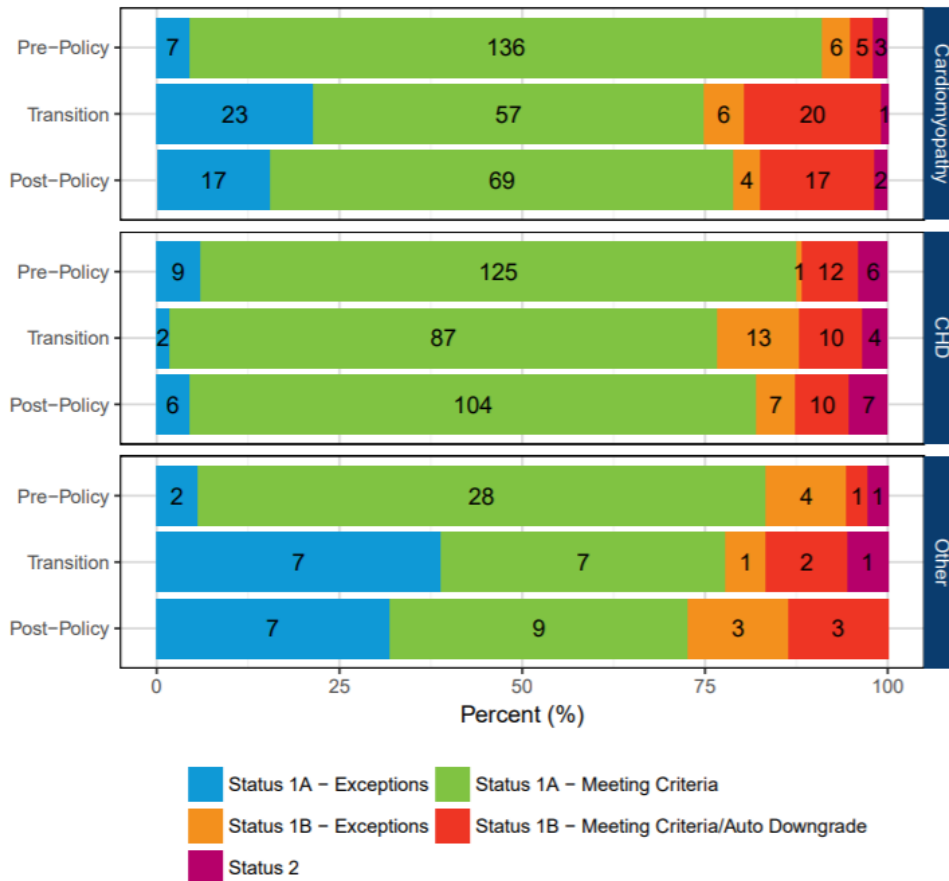
Figure 1 shows that candidates with diagnoses other than congenital heart disease (CHD) are being transplanted more often with a Status 1A exception since the implementation of the new Status 1A and 1B standards. Although the new criteria are having the intended result of decreasing the number of Status 1A and Status 1B that meet criteria, there has been an unintended result that the number of exceptions for candidates with the same diagnoses who do not meet the standard criteria for Status 1A is increasing. For example, under the old policy candidates with cardiomyopathy could qualify for status 1A. Under the new policy, there is no explicit sub-criterion in status 1A for candidates with cardiomyopathy. Therefore, post-implementation the Committee observed an increase in exception requests for status 1A based on a candidate's diagnosis of cardiomyopathy.

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<sup>8</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

<sup>9</sup> Final Report, *Changes to Pediatric Heart Allocation*, April 19, 2018, 21, Figure 17.

**Figure 1: Pediatric Heart Transplants by Exception Status, Era and Diagnosis<sup>10</sup>**



The report also identified an increase in the regional variation of the proportion of candidates transplanted while registered with a Status 1A exception. For instance, in Region 1, none of the pediatric heart transplants in the post-implementation cohort were transplanted at Status 1A by exception, while approximately 25% of the pediatric heart transplants in Region 3 were transplanted into candidates with a Status 1A exception. This suggests that some candidates may be disadvantaged in their ability to access an exception status based on their listing location.

## Proposal

The Committee proposes creating a NHRB specializing in pediatric Status 1A and Status 1B exception requests. The NHRB will be comprised of representatives of the pediatric heart programs across the nation and will decide all requests for pediatric heart Status 1A or Status 1B exceptions and exception extensions.

### Pediatric Specialty

Under *OPTN Policy 6.4, Adult and Pediatric Exceptions*, a candidate's transplant physician can register a pediatric heart candidate as Status 1A or Status 1B even though the candidate does not meet the

<sup>10</sup> Policy eras were defined as: Pre-Policy: March 22, 2015 to March 21, 2016; Transition: March 22, 2016 to September 30, 2016; Post-Policy: October 1, 2016 to December 31, 2017.

standard criteria in policy to automatically qualify for the status. When the transplant physician does this, they must submit a justification form with the requested status and the rationale for granting the status exception. Such requests are reviewed retrospectively by the appropriate Regional Review Board (RRB).

Pediatric transplantation is an accepted subspecialty within the field of transplantation,<sup>11</sup> but pediatric programs are often under-represented on a given heart RRB. For instance, in Region 4, there are 13 heart transplant programs that can each assign a representative and an alternate to participate on the RRB. As shown in *Table 1* below, of those programs, only two have listed at least one pediatric heart candidate within an 18 month span. As a result, each case decided by the Region 4 RRB is likely decided primarily by reviewers who do not typically transplant pediatric candidates.

**Table 1: Number of programs by OPTN region that listed at least one heart candidate on the waiting list between 1/1/2018 and 6/30/2019<sup>12</sup>**

OPTN Region	Heart Programs <sup>13</sup>	Heart Programs with at least one pediatric candidate listed <sup>14</sup>	% of Heart programs that have at least one pediatric candidate listed
1	6	2	33%
2	16	6	38%
3	19	11	58%
4	13	2	15%
5	20	9	45%
6	4	2	50%
7	13	8	62%
8	11	6	55%
9	7	2	29%
10	13	8	62%
11	17	8	47%

Members of the Thoracic and Pediatric Committees expressed concerns that this results in such requests receiving less scrutiny and the RRB members deferring more to the judgment of the requesting physician when granting an exception than they would when evaluating exception requests for adult candidates. For this reason, the Thoracic and Pediatric Committees favor using only pediatric specialists to review exception requests for pediatric candidates.

<sup>11</sup> Public Comment Proposal, *Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws*, OPTN/UNOS Pediatric Transplantation Committee, August 2015, [https://optn.transplant.hrsa.gov/media/1181/0815-01\\_pediatric\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1181/0815-01_pediatric_bylaws.pdf) (accessed November 14, 2019).

<sup>12</sup> *Heart Review Board Report*, October 2019. *Heart Review Board Report*, July 2019.

<sup>13</sup> Programs in each OPTN region that listed at least one heart candidate on the waiting list between 1/1/2018 and 6/30/2019

<sup>14</sup> Programs in each OPTN region that listed at least one pediatric (age at time of listing <18) heart candidate on the waiting list between 1/1/2018 and 6/30/2019



## Rationale for a National Board

Heart programs with pediatric specialty expertise have not historically been tracked by the OPTN. However, new requirements to delineate which programs are permitted to perform pediatric transplants have been approved by the Board, and are expected to be implemented in late 2020 or early 2021.<sup>15</sup> Although the specific number of programs that will have a pediatric heart component once the membership requirements are implemented is unknown, 53 heart transplant programs have applied for that designation as of the initial deadline<sup>16</sup>. They are not evenly distributed across regions.<sup>17</sup>

If pediatric specialty boards were created within the existing RRB system, there are regions where only one or two pediatric programs would be represented. The Committee did not consider it practical to have a regional review board with only one or two representatives.

Further, there is already regional variation in the percentage of candidates being transplanted with exceptions for Status 1A, as shown in Figure 2 below.<sup>18</sup> The Final Rule requires that allocation policies “not be based on the candidate’s place of residence or place of listing, except to the extent required...”.<sup>19</sup> Accordingly, the Thoracic Committee chose to remove the considerations for the place of listing in the evaluation of pediatric Status 1A and Status 1B exception requests.

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<sup>15</sup> Briefing Paper, *Revisions to Pediatric Emergency Membership Exception Pathway*, Pediatric Transplantation Committee, December 2017, available at [https://optn.transplant.hrsa.gov/media/2337/pediatric\\_boardreport\\_201712.pdf](https://optn.transplant.hrsa.gov/media/2337/pediatric_boardreport_201712.pdf).

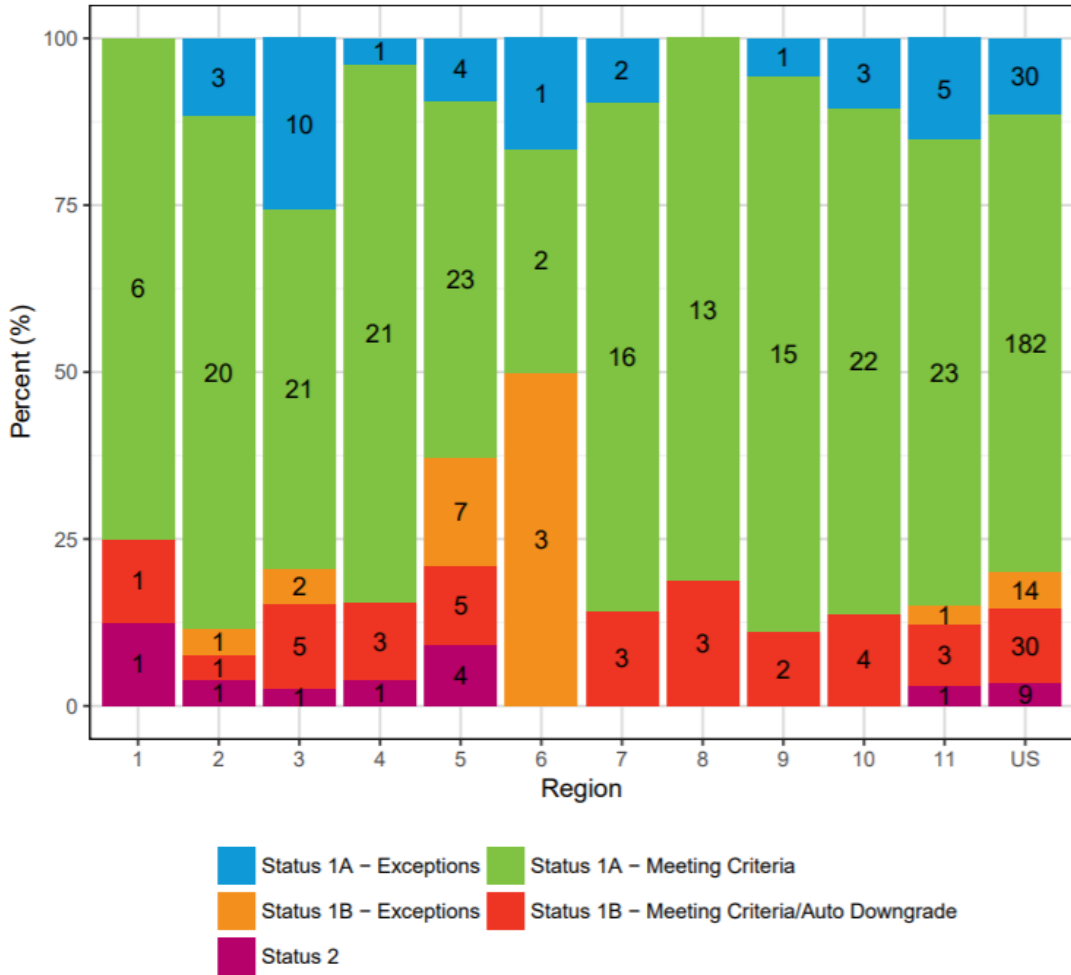
<sup>16</sup> The initial deadline to apply was December 3, 2019. On that date, 53 heart programs had applied, 20 programs had stated that they did not intend to apply, and 20 other programs were identified as likely potential applicants, but have not applied.

<sup>17</sup> See Table 1 above.

<sup>18</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*.

<sup>19</sup> 42 CFR 121.8(a)(8).

**Figure 2: Pediatric Heart Transplants by Region and Exception Status, 10/01/2016-12/31/2017**



The Thoracic Committee chose to create a national review board in order to provide more equitable access to Status 1A and 1B and to facilitate efficient and practical review of these requests by pediatric heart transplant specialists.

## Operations

This proposal would create a NHRB that would review Status 1A and Status 1B exception requests for pediatric heart candidates. The Committee considered whether it was only needed for Status 1A, which is the larger proportion of the exception requests for pediatric candidates. The Committee chose to have the NHRB review both Status 1A and 1B exception requests because both would benefit from the pediatric expertise the NHRB would bring. However, the Committee seeks feedback on whether the Status 1B requests should continue to be reviewed by the RRBs instead of the proposed NHRB.

## Representation

Each heart program with an active pediatric component will be able to appoint a primary representative and an alternate to the NHRB. They will serve for a one year term and may be reappointed for additional terms.

Exception requests will be assigned to nine randomly selected reviewers from the pool of current reviewers. The Committee considered whether there is a need for additional constraints on the random assignment, such as ensuring that reviewers are assigned even amounts of exceptions, or ensuring representation from:

- Different geographic areas (north and south, different regions, etc.)
- Both small and large programs.

The Thoracic Committee did not include such restraints, but requests additional feedback on whether there should be any criteria to the random reviewer assignments.

The Thoracic Committee chose nine reviewers for each case for several reasons. The volume of cases to review is expected to be too large to have all reviewers review every case, but small enough that there was not significant concern about overburdening reviewers if nine are assigned to each case. Nine was preferred over a smaller number because the larger number might be expected to provide more consistency. Finally, it was preferred over a larger number because the Thoracic Committee expects that this will decrease the likelihood of a decision being delayed to wait for one or two slow reviewers to respond.

The exception will be approved or denied based on the vote of the majority of those nine reviewers. If a reviewer votes to deny an exception, they will be expected to provide a reason that the requesting transplant program can review. The Committee intends for reviewers to provide explanations that will help the requesting transplant center improve future exception requests or appeals.

Reviewers will be expected to report the times when they will be unavailable to vote on exception requests. A representative may be removed for failure to vote if three of the exceptions they are assigned within a year are reassigned because the representative did not vote in time. This is intended to ensure that the reviewers are responsive so that transplant programs can receive an expeditious answer to exception requests.

## Voting

Because Status 1A and Status 1B are reserved for the most medically urgent pediatric heart candidates, with the highest waiting list mortality,<sup>20</sup> and the number of exceptions each year is not large<sup>21</sup>, the Committee chose a quick timeline for review. Reviewers must vote within three calendar days. The national average number of calendar days between assigning a case and closing it with sufficient votes for the RRBs was less than 2 days between May 2019 and October 2019, suggesting that three days is not an unreasonable timeline to expect reviewer responses. Further, Status 1A and 1B exceptions are

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<sup>20</sup> Colvin, M., Smith, J. M., Hadley, N., Skeans, M. A., Uccellini, K., Lehman, R., Robinson, A. M., Israni, A. K., Snyder, J.J. & Kasiske, B. L. OPTN/SRTR 2017 Annual Data Report: Heart. *Am J Transplant* 2019; 19 (Suppl 2): 323– 403. doi: [10.1111/ajt.15278](https://doi.org/10.1111/ajt.15278), Figure HR85: Pretransplant mortality rates among pediatrics waitlisted for heart transplant by medical urgency.

<sup>21</sup> In July, August and September 2019, there were 29, 19, and 25 pediatric Status 1A exception applications respectively. In the same months, there were 8, 11, and 9 pediatric Status 1B exception applications. *Heart Review Board Report*, October 2019.

reviewed retrospectively because these cases are so urgent that the candidates are awarded the status while waiting on a decision. Therefore, the longer a review board takes to reach a decision, the higher the likelihood that a candidate might be transplanted at a status that will ultimately be denied, resulting in disadvantage to other candidates in that status.

If the reviewer does not vote within one day, their alternate will be notified and either the primary reviewer or their alternate may vote on that request. If neither has voted after the third day, the exception request will be reassigned to another reviewer. If both vote before the request is closed, the primary reviewer's vote will be counted and the alternate's vote will not.

The exception will be closed when the first one of these occurs:

- There are five votes to approve
- There are five votes to deny
- Six days after the exception was requested

If the exception request is closed after six days, the exception will be decided based on the majority of the reviewers who responded within that time. If there is a tie, the exception will be granted. The Committee specifically requests feedback on whether a tie should result in approval, denial, or if the chair of the NHRB should break ties.

Currently, the voting process is manual, and managed by OPTN staff. This would change the process so that voting will occur in UNet<sup>SM</sup>. A new system to review and record exception request votes will be created in UNet that will assign reviewers and track votes. Reviewers will also be able to report the times when they will be unavailable within the system.

## Appeals

If the exception request is denied, the transplant program may appeal to the same group of nine reviewers, and provide additional information or answer any questions raised in the reviewer feedback. That request will once again be decided based on the majority vote by the reviewers. If there is no resolution within six days, the appeal will be decided based on the majority of those responding. If there is a tie, the appeal will be approved.

If the reviewers deny both the initial application and the appeal, the transplant program will have the option to submit a written appeal to a workgroup comprised of the members of the Thoracic and Pediatric Committees who have pediatric heart transplantation experience. If there are not at least five collective members with this expertise, the Thoracic Committee chair will appoint additional members to the workgroup who have pediatric heart transplantation expertise in order to have a sufficient number to decide appeal cases. The Committee considered whether the members of the workgroup need to be physicians or surgeons, since there might be transplant family or OPO representatives on either committee. Instead of making a rule on the specific qualifications, the Committee chose to allow the Thoracic Committee chair to make determinations about whether members have sufficient expertise. The Thoracic Committee specifically requests feedback on whether there should be additional requirements for participation on the workgroup, such as a requirement to be a physician or surgeon. The Thoracic Committee also seeks feedback on whether the Thoracic Committee chair is the appropriate position to decide who may be added to the review group in order to ensure that there are enough representatives.

If the appealing transplant program or a member of the workgroup requests, the appeal will be considered during a teleconference. If there is no request, it will be considered electronically.

These appeals will be decided by the vote of the majority of the members of that workgroup. If the appeal is considered on a teleconference, it will be decided by a majority of the members of the workgroup who participate in the teleconference. If there is a tie, the exception will be granted.

The Thoracic Committee considered allowing an additional level of appeal, but decided that the workgroup would provide sufficient oversight. The Thoracic Committee requests feedback on whether there should be another level of appeal available to transplant centers whose request is denied by the workgroup. If another level of appeal is warranted, then the Committee requests feedback on the appropriate body to consider those appeals.

## Guidance

The Thoracic Committee also plans to produce a guidance document to be circulated for additional public comment later this year. It would assist transplant programs and reviewers regarding the most common diagnoses for which Status 1A is requested. The guidance document is expected to be completed and available before the implementation of the NHRB. The Thoracic Committee intends to include guidance on evaluation of candidates with cardiomyopathy. Feedback is requested on whether there are additional diagnoses that warrant guidance.

## Feedback Questions

The Committee welcomes additional feedback on the operation of the NHRB, including the following:

### Composition

1. Should there be criteria for randomization of reviewer assignment? (for instance, requirements to make sure there is a certain geographic representation, or balance of small and large centers, or ensure that numbers of cases are fairly evenly distributed).). If yes, what would need to be included?
2. Should there be other requirements for who can be on the NHRB? For instance, should the transplant program or the physician be required to have performed at least a certain number of pediatric heart transplants in the last year, or should they be required to be a physician or surgeon?
3. Is there a need for a chair of the NHRB? If so, should the chair of the NHRB be appointed by the Thoracic Committee chair and serve a two year term? Should the chair be randomly assigned cases and vote on them as a member of the NHRB? What role would the chair serve?
4. Who should determine the members of the appeal workgroup?

### Voting

5. Is three days the right length of time to vote?
6. Is there a need for an additional level of appeal, such as to the entire Thoracic Committee?
7. Is nine the correct number of reviewers to consider each application?
8. Does the alternate need to be notified and allowed to vote on cases that have been sent to the primary reviewer?

9. When both a primary and alternate representative vote on a case in the RRB system, the first vote is counted. The Thoracic Committee proposes that the primary representative's vote be the vote that counts in that situation under the NHRB. Should it be the same for both boards, and if so, which vote should count?
10. Is a simple majority the right threshold for approval?
11. Did the Committee choose the correct tiebreakers?
  - a. Should the tiebreaker be the same on appeal as it is in the initial review?
  - b. Would it be better to have a chair of the workgroup break ties when a case is appealed to that level?
  - c. Should the exception request be denied when there is a tie instead of being approved?
12. Should there be a time limit for how quickly the Thoracic committee review will take place if an application is appealed to that level?
13. If a member of the Committee-level appeal workgroup has already reviewed the application as a reviewer on the NHRB, should that reviewer participate in the review of the appeal or not? Should others be excluded from the review?

### **Removal for failure to vote**

14. Is three the right threshold for removal for failure to vote on an application? Should it be based on a percentage instead?
15. Is two reviewers removed from the review board the right number for removing a program's ability to appoint a member for the review board? Should it be within a certain time frame (such as two within a one-year term, or two within 5 years?)

### **Other**

16. Which diagnoses should be addressed in guidance?
17. Are the right data points for evaluating the effectiveness of the review board identified in the Post Implementation Monitoring section below?
18. Are there any other areas in which the NHRB should change to align with the way the RRBs or other organ review boards operate?
19. Should the Thoracic Committee consider using a NHRB for review of adult exception requests as well?

### **Potential Impact on Select Patient Populations**

This proposal will directly affect pediatric heart candidates. Specifically, it is expected to change approval rates for pediatric heart candidates applying for a Status 1A or Status 1B exception. If fewer exceptions are approved for these candidates, the candidates who are approved for Status 1A or 1B based on the policy criteria will likely be transplanted earlier. As shown in Figure 1 above, over a 20 month period, there were 40 transplants into recipients who were Status 1A or Status 1B by exception. During the same period, 212 recipients were transplanted while listed as Status 1A or Status 1B based on the standard policy criteria.

### **Alternate Solutions Considered**

The Committee considered eliminating the RRBs and having all exceptions reviewed by the NHRB, including those for adult candidates. However, the Committee chose to pursue a NHRB only for pediatric

candidates at this time in order to more quickly address the difficulties experienced by this particular population.

The Committee also considered releasing guidance to assist the RRBs with evaluation of the most common diagnoses without also changing the reviewers. The Committee decided to create this guidance, and expects to release a draft for public comment later this year. The Committee chose to pursue the guidance in conjunction with a NHRB because no guidance can anticipate every situation, and pediatric expertise will be particularly important for evaluating the cases that are not directly covered by the guidance.

## NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed “in accordance with §121.4”, which in turn incorporates the requirements in §121.8. This proposal addresses the following requirements of the Final Rule.

- **Shall be based on sound medical judgment:** The Committee proposes this change based on the medical judgment that candidates within the same status should have similar medical urgency, and data that shows there are variances in Status 1A listings by region, and variances in Status 1A waiting list mortality depending on whether the candidate is listed as a Status 1A based on policy criteria or an exception, and an increase in the number of Status 1A exceptions.
- **Shall seek to achieve the best use of donated organs:** The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to make the best use of donated organs by allocating them for the most medically urgent candidates first.
- **Shall be designed to...promote patient access to transplantation:** This proposal promotes pediatric heart candidate access to transplants by assigning review of their exception requests to a single national board in order to reduce variance in their access to Status 1A and Status 1B based on which RRB reviews their request.
- **Shall not be based on the candidate’s place of residence or place of listing, except to the extent required [ other regulatory criteria]:** This proposal removes the consideration of place of listing from determining which review board will review the candidate’s Status exception request.

## Implementation and Operational Considerations

### OPTN Actions

This proposal will require programming in UNet<sup>SM</sup>. The OPTN will set up the operating structure, including case assignments and criteria, developing new forms, and onboarding reviewers.

This proposal may require instructional support. UNOS staff will continue to monitor this need throughout the discussion and development of the proposal.

## Member Actions

Pediatric heart transplant programs may appoint a representative and an alternate to both the RRB and the pediatric NHRB. This may result in reviewers from those institutions having to vote in two heart review board systems.

Pediatric heart transplant programs may also need to train staff in changes to the forms for exception requests.

Minimal or no fiscal impact is expected for members.

## Post-implementation Monitoring

### Member Compliance

The proposal will not change the current routine monitoring of OPTN members. Any data entered into UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.

### Policy Evaluation

The Final Rule requires allocation policies to be “reviewed periodically and revised as appropriate.”<sup>22</sup> The following evaluation plan will provide the Committees with information on a periodic basis about whether the policy is achieving its goals, and whether any revisions are warranted.

This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy.

- Examine changes in the number and percent of pediatric candidates by status, exception, age group, OPTN region, and diagnosis
- Examine changes in the number and percent of pediatric transplant recipients by status, exception, age group, OPTN region, and diagnosis
- Evaluate changes in waiting list mortality rate for pediatric candidates by status and exception
- Evaluate changes in transplant rate for pediatric candidates by status and exception
- Report the percent of approvals and denials for exception requests by status
- Examine changes in post-transplant patient survival rates overall and stratified by status

## Conclusion

The Thoracic Committee proposes the creation of the NHRB for pediatrics to improve consistency in reviews, reduce variance in the volume of transplants for Status 1A candidates by region, and reduce the variance in waiting list mortality within a status.

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<sup>22</sup> 42 CFR 121.8(a)(6).



## Policy 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 **6.4 Adult and Pediatric Status Exceptions**

2 A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

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**Table 6-3: Exception Qualification and Periods**

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1	<ol style="list-style-type: none"> <li>Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</li> <li>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</li> </ol>	RRBs retrospectively review requests for status 1 exceptions	14 days	<ul style="list-style-type: none"> <li>Require RRB approval for each successive 14 day period</li> <li>RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 2	<ol style="list-style-type: none"> <li>Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</li> <li>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</li> </ol>	RRBs retrospectively review requests for status 2 exceptions	14 days	<ul style="list-style-type: none"> <li>Require RRB approval for each successive 14 day period</li> <li>RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 3	<ol style="list-style-type: none"> <li>Candidate is admitted to the transplant</li> </ol>	RRBs retrospectively	14 days	<ul style="list-style-type: none"> <li>Require RRB approval for each</li> </ul>

	<p>hospital that registered the candidate on the waiting list</p> <p>2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</p>	<p>review requests for status 3 exceptions</p>		<p>successive 14 day period</p> <ul style="list-style-type: none"> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 4	<p>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</p>	<p>RRBs retrospectively review requests for status 4 exceptions</p>	90 days	<ul style="list-style-type: none"> <li>• Require RRB approval for each successive 90 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Pediatric status 1A	<ul style="list-style-type: none"> <li>• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</li> <li>• Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</li> </ul>	<p><u>The national heart review board (NHRB)</u> <del>RRBs</del> retrospectively reviews requests for Status 1A-exceptions</p>	14 days	<ul style="list-style-type: none"> <li>• Require <u>The NHRB</u> approval for each successive 14 day period</li> <li>• <u>The NHRB RRB</u> will review and decide extension requests retrospectively</li> <li>• If no extension request is submitted, the candidate will be assigned pediatric status 1B</li> </ul>
Pediatric status 1B	<p>Transplant physician believes, using acceptable medical criteria, that a heart</p>	<p><u>The NHRB</u> <del>RRBs</del> retrospectively reviews requests for</p>	Indefinite	<ul style="list-style-type: none"> <li>• Not required as long as candidate's</li> </ul>

	candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	Status 1B exceptions		medical condition remains the same
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5  
6 The candidate’s transplant physician must submit a justification form to the OPTN Contractor with the  
7 requested status and the rationale for granting the status exception.

8  
9 **6.4.A Review Board RRB and Committee Review of Status Exceptions**

10 The heart RRB reviews applications for adult and pediatric status exceptions and extensions  
11 retrospectively. The national heart review board (NHRB) reviews applications for pediatric status  
12 exceptions and extensions retrospectively.

13  
14 If the candidate is transplanted and the relevant review board RRB does not approve the initial  
15 exception or extension request or any appeals, then the case will be referred to the Thoracic  
16 Committee. If the Thoracic Committee agrees with the review board’s RRB’s decision, then the Thoracic  
17 Committee may refer the case to Membership & Professional Standards Committee (MPSC) for review  
18 according to *Appendix L* of the OPTN Bylaws.

19  
20 **6.4.A.i. Review Board RRB Appeals**

21 If the review board RRB denies an exception or extension request, the candidate’s  
22 transplant program must either appeal to the relevant review board RRB within 1 day of  
23 receiving notification of the review board RRB denial, or assign the candidate to the status  
24 for which the candidate qualifies within 1 day of receiving notification of the review board  
25 RRB denial.

26  
27 **6.4.A.ii Committee Appeals**

28 If the review board RRB denies the appeal, the candidate’s transplant program must within  
29 1 day of receiving notification of the denied appeal either appeal to the Thoracic Organ  
30 Transplantation Committee or assign the candidate to the status for which the candidate  
31 qualifies. If the Thoracic Committee agrees with the review board’s RRB’s decision, the  
32 candidate’s transplant program must assign the candidate to the status for which the  
33 candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If  
34 the transplant program does not assign the candidate to the status for which the candidate  
35 qualifies within 1 day of receiving notification of the denied Committee appeal, then the  
36 Committee will refer the case to the MPSC.

37

## Operational Guidelines Language

### National Heart Review Board Pediatrics Operational Guidelines

#### Overview

The purpose of the National Heart Review Board (NHRB) for pediatrics is to provide fair, equitable, and prompt peer review of pediatric candidate status 1A- and status 1B- justification form applications submitted by transplant programs for candidates whose medical urgency is not accurately reflected by the standard pediatric listing criteria for heart allocation. Justification form applications will be referred to throughout these guidelines as “applications” and include initial submissions, extension requests, and appeals.

#### Representation

Each heart transplant program with an active pediatric component may appoint a representative and an alternate to the NHRB. Transplant programs are encouraged to appoint representatives from both cardiology and cardiac surgery who have active pediatric heart transplant experience. Heart transplant programs are not required to appoint a representative to the NHRB.

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

If a transplant hospital withdraws or inactivates its heart transplant program or the pediatric component, it may not participate in the NHRB. However, the transplant hospitals’ participation may resume once it has reactivated the transplant program and the pediatric component.

If at any time, a representative is no longer eligible to review applications, that application may be randomly reassigned to another reviewer.

#### Representative and Alternate Responsibilities

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

Representatives must vote within three days on all exception requests, exception extension requests, and appeals. A representative will receive an e-mail reminder after day 1 and day 2 if the representative has an outstanding vote that must be completed.

At the end of the first day, the alternate will be notified of the open application and either the primary or alternate will be able to vote on that application. Only one vote from any program will count. If both the primary and the alternate from the same program respond before the application is closed, only the primary representative’s vote will be counted.

42 After three days, if neither the primary nor their alternate has voted, then the request will be randomly  
43 reassigned to a representative from another program. The primary reviewer and alternate will receive a  
44 notification that the request has been reassigned.

45  
46 Representatives must notify UNOS in advance of absences, during which the alternate will fulfill the  
47 responsibilities of the representative.

48  
49 If a representative or alternate does not vote on an open request within three days on three separate  
50 instances within a 12 month period, the Chair may remove the individual from the NHRB. If a  
51 representative or alternate does not vote because a case is approved and closed before the three day  
52 timeframe expires, it is not considered a failure to vote. A representative or alternate who has been  
53 removed for failure to perform the duties required is not eligible to serve again for three years.

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

60  
61 **Voting Procedure**

62 Each exception request is assigned to a randomly generated group of nine representatives of the NHRB.  
63 A representative may vote to approve or deny the request, or ask that the request be reassigned.

64  
65 Voting will close at the earliest of when:

- 66 • 5 reviewers have voted to approve a request;
- 67 • 5 voters have voted to deny a request; or
- 68 • 6 days after the first NHRB reviewer receives the request

69  
70 When voting is closed, NHRB review of applications are decided as described in Table 1, below:

71  
72 **Table 1: Effect of NHRB Votes**

<b><u>Of the votes submitted, if...</u></b>	<b><u>Then the application is...</u></b>
<u>Majority vote to approve</u>	<u>Approved</u>
<u>An equal number of voters have voted to approve as deny</u>	<u>Approved</u>
<u>Majority vote to not approve</u>	<u>Not approved</u>

73  
74 Representatives no longer have the ability to vote once voting is closed.

75  
76 **Appeal Process**

77 A pediatric heart transplant program may appeal the NHRB decision to deny an exception request.  
78 Patients are not eligible to appeal exception requests. All reviewer comments are available in UNet<sup>SM</sup>.  
79 The NHRB advises programs to respond to the comments of dissenting reviewers in the appeal.

80

81 Each appeal is assigned to the same group of nine representatives that reviewed the exception  
82 application. A representative may vote to approve or deny the request, or ask that the request be  
83 reassigned.

84

85 Voting will close at the earliest of when:

- 86 • 5 reviewers have voted to approve a request;
- 87 • 5 voters have voted to deny a request; o
- 88 • 6 days after the first NHRB reviewer receives the request

89

90 When voting is closed, appeals are decided as described in Table 2, below:

91

92

**Table 2: Effect of NHRB Appeal Votes**

<b><u>Of the votes submitted, if...</u></b>	<b><u>Then the application is...</u></b>
<u>Majority vote to approve</u>	<u>Approved</u>
<u>An equal number of voters have voted to approve as deny</u>	<u>Approved</u>
<u>Majority vote to not approve</u>	<u>Not approved</u>

93

94

95 If the appeal is denied, the pediatric heart program may initiate a final appeal to the Thoracic Organ  
96 Transplantation Committee (Thoracic Committee)

97

## 98 **Thoracic Committee Appeals**

99 The Thoracic Committee may delegate review of appeals to a workgroup of at least five members which  
100 may consist of members of the Thoracic Committee, Pediatric Committee, or other pediatric heart  
101 physicians or surgeons.

102

103 If the appeal achieves a majority affirmative votes, it will be approved. In the event of a tie, the appeal  
104 will be approved. The initial request will be made in writing. If either the program or a representative  
105 requests that the appeal be considered on a conference call, then a call will be scheduled with the  
106 workgroup.

107

## OPTN Heart Review Board (HRB) Guidelines

### 1. Overview

The purpose of the Heart Review Board (HRB) is to provide fair, equitable, and prompt peer review of adult candidate status 1-4 and ~~pediatric candidate status 1A and status 1B~~ justification form applications submitted by transplant programs. Justification form applications will be referred to throughout these guidelines as “applications” and include initial submissions, extension requests, and appeals.

### 2. Representation

- A. Every designated heart transplant program may participate on the HRB. Each HRB will consist of a minimum of representation from three programs.
- B. The Regional Councillor or the Councillor’s designee selects a heart transplant physician or surgeon affiliated with a designated heart transplant program within his or her OPTN region to serve as the HRB Chair. The HRB Chair will be called upon to decide tie votes and may not simultaneously represent his or her transplant program as an HRB member.
- C. The HRBs vary in size and rotate as determined by each OPTN region. Since larger HRBs may pose operational or administrative challenges, some HRBs rotate membership to ensure each transplant program is represented on the HRB for one term each year.
- D. Each program represented on the HRB must identify one primary and at least one alternate representative ~~to the OPTN Contractor~~. It is the responsibility of each transplant program to provide ~~the OPTN Contractor with~~ the contact information for both the HRB primary and alternate representatives. Should an HRB primary representative leave his or her transplant program, then the transplant program’s alternate representative will become the new HRB primary representative, and the program must provide ~~the OPTN Contractor with~~ the contact information for another alternate representative. The program can also choose to keep the existing alternate representative and provide ~~the OPTN Contractor with~~ the contact information for a new RB primary representative.
- E. If a transplant hospital inactivates or withdraws its heart program, it may not participate in the HRB. The term of the transplant program’s representative on the HRB ends upon program’s inactivation or withdrawal from the OPTN. However, the transplant hospital’s participation may resume once it has reactivated its heart program.

#### 1. Responsibilities of HRB representatives

HRB primary and alternate representatives must:

- A. Complete the OPTN/UNOS Confidentiality Agreement and Certification Regarding Conflicts of Interest form prior to serving on the HRB.

- 44           B. Evaluate the eligibility criteria of other approved applications to achieve consistency in  
45           decision-making and determine whether this candidate meets similar levels of medical  
46           urgency and potential for benefit.
- 47           C. Vote to approve or not approve applications according to the timelines specified in the  
48           guidelines below. When voting to “not approve” an application, the voter should provide  
49           comments or questions to the program submitting the application to support the vote.  
50

## 51 **4. Voting Procedures**

### 52 **A. Retrospective Review of Status Exceptions**

53           The HRB will review all applications that require HRB review retrospectively. During the entirety of  
54           the retrospective review, extension, and/or appeal process, the candidate’s status will be equal to the  
55           requested status and the transplant program must follow all OPTN policies applicable to the  
56           requested status.  
57

58           At the termination of the application or appeal process, if the requested status is not approved, then  
59           the transplant program must change the candidate’s status to the status for which the candidate  
60           qualifies under policy within 1 day of receiving notification of denial or initiate an appeal as described  
61           below.  
62

### 63 **B. Eligibility to Vote**

64           An HRB primary or alternate representative’s vote will not be valid and will not count towards a  
65           quorum in any case in which the member has a conflict of interest.  
66

### 67 **C. Regional Rotation**

68           The HRB will review applications from another OPTN region on a rotating basis. The same HRB that  
69           reviewed an initial application will review extension requests and appeals associated with the  
70           candidate, with the exception of applications that are extended or appealed after the regional  
71           rotation to different regions occurs.  
72

### 73 **D. HRB Case Review and Vote**

74           ~~The OPTN Contractor will first send all applications~~ All applications will first be sent to the HRB primary  
75           representative. If the primary representative has not voted within 3 business days ~~of when the OPTN~~  
76           ~~Contractor sends the application to the HRB~~ of the HRB receiving the application, then ~~the OPTN~~  
77           ~~Contractor will send the case~~ will be sent to the alternate representative. Thereafter, both the HRB  
78           member and alternate representative may vote on the application within 7 days of when the ~~OPTN~~  
79           ~~Contractor originally sent the application~~ application was originally provided to the HRB. If the HRB  
80           member and the alternate representative both submit votes for the same application, then the OPTN  
81           ~~Contractor will count~~ the vote from whomever voted first will be counted.  
82

83           In order for a decision to be rendered, a majority vote is required. A majority vote requires more than  
84           half of the HRB representatives (or their alternates) voting on the application. If all HRB representative  
85           have voted and the vote is tied, the HRB chair will be contacted to break the tie.  
86



- 91 Voting will close at the earliest of when:
- 92 • all eligible voters have voted;
  - 93 • a majority of all eligible voters have voted to approve ~~or deny~~ a request
  - 94 • a majority of all eligible voters have voted to deny a request; or
  - 95 • 7 days after the ~~OPTN Contractor sends the request is sent~~ to the HRB
- 96
- 97 HRB review of applications (initial submissions, extensions, and appeals) are decided as described in
- 98 Table 1, below:
- 99
- 100

**Table 1: Effect of HRB Votes**

If the vote is...	Then the application is...
Majority vote to approve	Approved
All voters tied and HRB chair votes to approve	Approved
Majority vote to not approve	Not approved
<del>All voters tied</del> <u>An equal number of voters have voted to approve as deny</u> and HRB chair votes to not approve	Not approved
<del>All voters tied</del> <u>An equal number of voters have voted to approve as deny</u> and HRB chair does not break tie	Approved
No majority vote reached	Approved

101

102 Once voting is closed, a HRB member or alternate can no longer vote on that case.

103

104 The ~~OPTN Contractor~~ will maintain the results of the HRB’s vote. If an application is not approved,

105 the ~~OPTN Contractor~~ will notify the program that submitted the application and will provide the

106 transplant program with comments or questions made by the HRB members, but will not provide

107 the votes of specific HRB members.

108

109 **5. Appeal Process**

110 **A. Appeal to the Review Board**

111

112 If the HRB does not approve an initial or extension request application, the candidate’s transplant

113 program must either submit an appeal application to the HRB within 1 day of receiving notification

114 of the HRB decision, or assign the candidate to the status for which the candidate qualifies within 1

115 day of notification of the HRB’s decision.

116

117 The transplant program may submit additional written information justifying the requested

118 exception status, and may include responses to the comments of dissenting HRB members. This

119 additional information will be provided to HRB members for further consideration.

120

121 If the application is not appealed to the HRB within 1 day of receiving the notification of the HRB’s

122 decision, the appeal process is not available.

123

124           Appealed applications are adjudicated as described in **Table 1**, above.

125

## 126 **B. Appeals of HRB Denials to the Thoracic Committee and MPSC Review**

127

128           If the HRB denies the appeal of an initial application or extension request application, the  
129           candidate’s transplant program must either appeal to the Thoracic Organ Transplantation  
130           Committee within 1 day of receiving notification of the denied appeal or assign the candidate to the  
131           status for which the candidate qualifies within 1 day of notification of the denied appeal.

132

133           The transplant program may provide the OPTN ~~Contractor~~ with additional information about the  
134           case, which the OPTN ~~Contractor~~ will send to the Committee. The Committee will approve or not  
135           approve each appeal within 7 days of submission of the case to the Committee.

136

137           Referral of cases to the Committee will include information about the number of previous case  
138           referrals from that transplant program and the outcome of those referrals.

139

140           If the application is not appealed to the Thoracic Committee within one day of receiving the  
141           notification of the HRB decision, the appeal process is not available.

## 142 **6. Extensions**

143           The HRB will retrospectively review extension request applications. If an application will expire before the  
144           deadline for the HRB or Committee to decide on the application, and the transplant program submits a  
145           request for an extension of that application, then the HRB or Committee will vote on the extension  
146           application request, and the original application will be automatically closed out.

147

## 148 **7. Administration**

149           The central office for each HRB is maintained by the OPTN ~~Contractor~~. The HRB efforts are coordinated  
150           by the OPTN ~~Contractor~~.

151

152           Data sent to the HRBs for action or review will not contain hospital, program, or candidate identifying  
153           information.

154

155           HRB member responses may be shared with the transplant program if a HRB member specifically asks  
156           that comments be shared with the program, regardless of the voting outcome.