

Briefing to the OPTN Board of Directors on

National Heart Review Board for

Pediatrics

OPTN Thoracic Organ Transplantation Committee

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Contents

Executive Summary	2
Background	3
Purpose	7
Overall Sentiment from Public Comment	7
Proposal for Board Consideration	12
OPTN Final Rule Analysis	15
Alignment with OPTN Strategic Plan	16
Implementation Considerations	17
Post-implementation Monitoring	18
Conclusion	19
Policy Language	20
Operational Guidelines Language	23
National Heart Review Board for Pediatrics Operational Guidelines	23
OPTN Adult Heart Regional Review Board (RRB) Guidelines	26
Appendix A: Pediatric Heart Transplants by Region, Exception Status, and Timeframe Associated With Policy Changes Implemented in March, 2016	30

National Heart Review Board for Pediatrics

<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>OPTN Heart Review Board (HRB) Guidelines</i>
<i>Sponsoring Committee:</i>	<i>Thoracic Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>January 22, 2020 – March 24, 2020</i>
<i>Board of Directors Date:</i>	<i>June 8, 2020</i>

Executive Summary

A modification to heart policy redefining pediatric Status 1A and Status 1B criteria went into effect in March 2016.¹ When members of the Organ Procurement and Transplantation Network (OPTN) Thoracic Organ Transplantation Committee (Thoracic Committee) and members of the OPTN Pediatric Transplantation Committee (Pediatric Committee) reviewed the data from the first 12 months the new policy was in effect, they noted a marked increase in the use of exceptions to justify placing pediatric heart candidates in Status 1A.² The size of the increase varied by OPTN region, and it is believed the differences are influenced by regionally-separated review boards, with varying levels of pediatric expertise.

This proposal will create a national heart review board (NHRB) for pediatric heart candidates. Under the NHRB, each Status 1A and Status 1B exception request will be randomly assigned to a group of pediatric heart transplant specialists who will decide whether to approve the request. All pediatric heart transplant programs will have the opportunity to be represented on the NHRB, and cases will be assigned to a group of reviewers randomly selected from the pool of all pediatric heart transplant programs. By creating a single, national review board, the proposal seeks to

1. Draw on the specialized pediatric expertise of physicians and surgeons from around the country to refine the evaluation of Status 1A and Status 1B exception requests
2. Reduce the regional variance in volume of Status 1A and Status 1B exceptions.

¹ OPTN, Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018, p. 2.

² Ibid.

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 18.³ As part of its ongoing commitment to this population, the OPTN Board of Directors (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.⁴

After implementation of those changes, as part of its work to monitor their effectiveness, the members of the Thoracic and Pediatric Committees reviewed an evaluation report in April 2018 (Report).⁵ Findings in the Report 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. Information in the Report suggested that more waiting list additions and transplant recipients were in Status 1A by exception following the 2016 changes.⁶ 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.⁷ 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.

³ 42 U.S.C. 274(b)(2)(M).

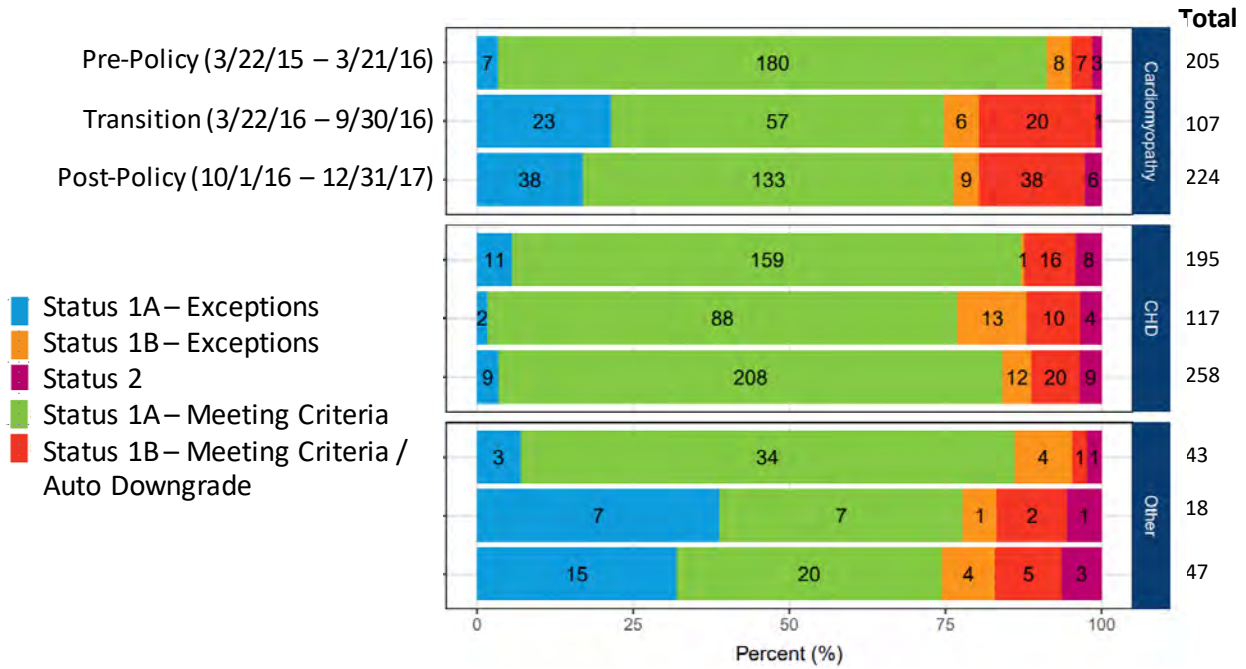
⁴ Briefing Paper, *Proposal to Change Pediatric Heart Allocation Policy*, Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee, April 2014.

⁵ OPTN, Final Report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

⁶ *Ibid*, p. 2.

⁷ *Ibid*, p. 21.

Figure 1: Pediatric Heart Transplants by Exception Status, Era and Diagnosis⁸



The report also identified an increase in the regional variation of the proportion of candidates transplanted while registered with a Status 1A exception⁹. As shown in **Table 1** for instance, in Region 1, none of the pediatric heart transplants in the post-implementation cohort were transplanted at Status 1A by exception, while 18 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.

Table 1: Pediatric Heart Transplants by Status 1A – Exceptions and Policy Era¹⁰

Implementation Timeframe	Regions											Total
	1	2	3	4	5	6	7	8	9	10	11	
Pre (3/22/15 – 3/21/16)	1	1	4	2	3	1	2	2	0	1	1	18
Transition (3/22/16 – 9/30/16)	0	3	3	1	6	1	7	2	4	3	2	32
Post (10/1/16 – 12/31/17)	0	3	18	2	7	1	6	5	4	7	9	62

Pediatric Specialty

Under *OPTN Policy 6.4: Adult and Pediatric Status 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 standard criteria in policy to automatically qualify for the status. When the transplant physician does

⁸ 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. Data revised February 18, 2020.

⁹ OPTN, Final Report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 9, 2018, p. 17.

¹⁰ IBID, pp. 15 – 17.

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,¹¹ 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 2** 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 2: Number of Programs by OPTN Region That Listed at Least One Heart Candidate on the Waiting List Between 1/1/2018 and 6/30/2019¹²

	OPTN Regions										
	1	2	3	4	5	6	7	8	9	10	11
Total Number of Heart Programs ¹³	6	16	19	13	20	4	13	11	7	13	17
Heart Programs Listing at Least One Pediatric Candidate	2	6	11	2	9	2	8	6	2	8	8
% of Heart Programs Listing Least One Pediatric Candidate	33%	38%	58%	15%	45%	50%	62%	55%	29%	62%	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.

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 2021.¹⁵

¹¹ OPTN, Briefing Paper, *Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws*, OPTN/UNOS Pediatric Transplantation Committee, December 2015, p. 3, https://optn.transplant.hrsa.gov/media/2074/policynote_20151201_pediatric_training_experience.pdf (accessed April 24, 2020).

¹² *Heart Review Board Report*, October, 2019. *Heart Review Board Report*, July 2019.

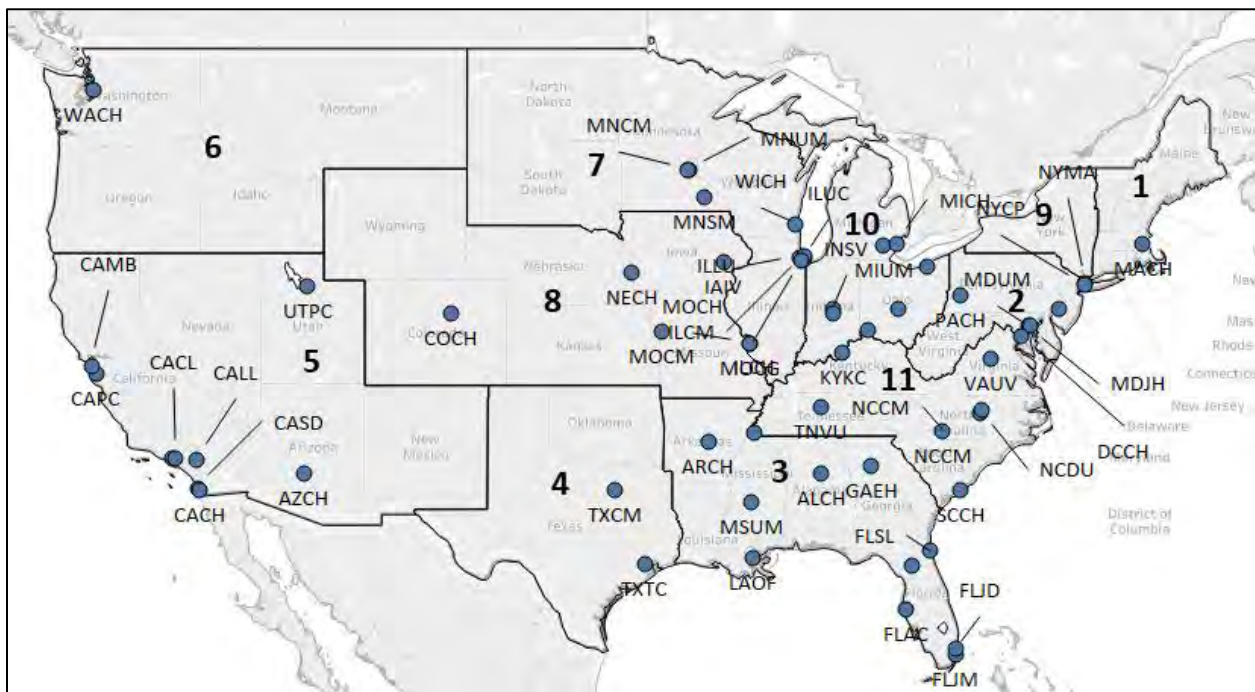
¹³ Programs in each OPTN region that listed at least one heart candidate on the waiting list between 1/1/2018 and 6/30/2019

¹⁴ 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

¹⁵ OPTN, Briefing Paper, *Revisions to Pediatric Emergency Membership Exception Pathway*, Pediatric Transplantation Committee, December 2017,

As discussed, the few pediatric heart transplant programs in the United States are not located evenly throughout the OPTN regions. As a result, some regional review boards have a limited number of pediatric heart transplant specialists from whom they can have serve on the board. **Figure 2**, shows the locations of heart transplant programs who transplanted at least one pediatric candidate from July 1, 2018 through June 30, 2019.¹⁶ While the figure does not capture all pediatric heart transplant programs, it can serve as a good proxy for their distribution. 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.

Figure 2: Transplant Programs That Performed at Least One Pediatric Heart Transplant From July 1, 2018 Through June 30, 2019



Note: The map in the figure does not include the western counties of Vermont within region 9. Nor does it include the localities in northern Virginia within region 2.

Further, there is already regional variation in the percentage of candidates being transplanted with exceptions for Status 1A.¹⁷ **Appendix A** shows the number of pediatric heart transplants by region and exception status during the pre-, transition, and post-implementation of the changes in pediatric heart policy in March 2016. The Final Rule requires that allocation policies “not be based on the candidate’s

https://optn.transplant.hrsa.gov/media/2074/policynotice_20151201_pediatric_training_experience.pdf (accessed April 24, 2020).

¹⁶ Scientific Registry of Transplant Recipients, Transplant Centers webpage filtered on heart programs and pediatric recipients, <https://www.srtr.org/transplant-centers/?query=&distance=50&location=&state=&recipientType=pediatric&organ=heart&sort=transplantRate> (accessed April 24, 2020).

¹⁷ OPTN, Final Report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 9, 2018

place of residence or place of listing, except to the extent required...” by other considerations explicitly listed in the Final Rule.¹⁸ 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 by creating a single national heart review board that gives all pediatric programs the same opportunity to review a request, and the same opportunity for their request to be reviewed by pediatric heart transplant specialists nationwide. In addition, a national review board is expected 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.

Purpose

The purpose of the proposal to create a National Heart Review Board (NHRB) is to improve quality and consistency in the evaluation of exceptions for heart candidates listed before their 18th 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.¹⁹

The members of the Thoracic Committee and the Pediatric Committee concluded 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.²⁰

The NHRB would be comprised of representatives from pediatric heart programs from across 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 seek to minimize local differences and improve consistency. The improvements will better align with the Final Rule’s performance goal of ranking patients from most to least medically urgent by clarifying the circumstances under which it is appropriate to use and approve exceptions to the standard criteria.²¹ Such clarifications will help ensure hearts are provided to the sickest pediatric candidates first.

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”²²

Overall Sentiment from Public Comment

The proposal was available for public comment from January 22 through March 24, 2020. During that time, 27 comments were submitted to the OPTN website. The entries included summaries of the 11 regional meetings and the Pediatric Committee where the proposal was discussed. The remaining 15 entries were submitted by individuals, and on behalf of transplant programs, professional organizations,

¹⁸ 42 CFR §121.8(a)(8) 2020.

¹⁹ OPTN Policy 6.2 Pediatric Status Assignments and Update Requirements

²⁰ For purposes of this paper, pediatric candidates refers to candidates registered for a heart transplant before their 18th birthday.

²¹ 42 CFR §121.8(b)(2).

²² 42 CFR §121.4(a).

and a patient advocacy organization. When combined with the sentiment voting conducted at the regional meetings and the Pediatric Committee, the proposal received more than 250 comments. The proposal received strong support in all eleven regional meetings, and from members of the Pediatric Committee. Of the 215 sentiment votes cast, 184, or 86 percent, indicated support for the proposal, with roughly 34 percent strongly supportive.

As shown in **Figure 3**, a total of 207 sentiment votes were submitted as part of the 11 regional meetings. Overall, four regions (2, 3, 5, and 8) accounted for almost half of the sentiment votes. The most votes were cast in Region 5 and Region 2. Region 1 and Region 9 accounted for the fewest votes. Regions 9,10, and 11 were changed to virtual meetings due to the COVID-19 pandemic.

Figure 3: Sentiment Support for the Proposal, by Region

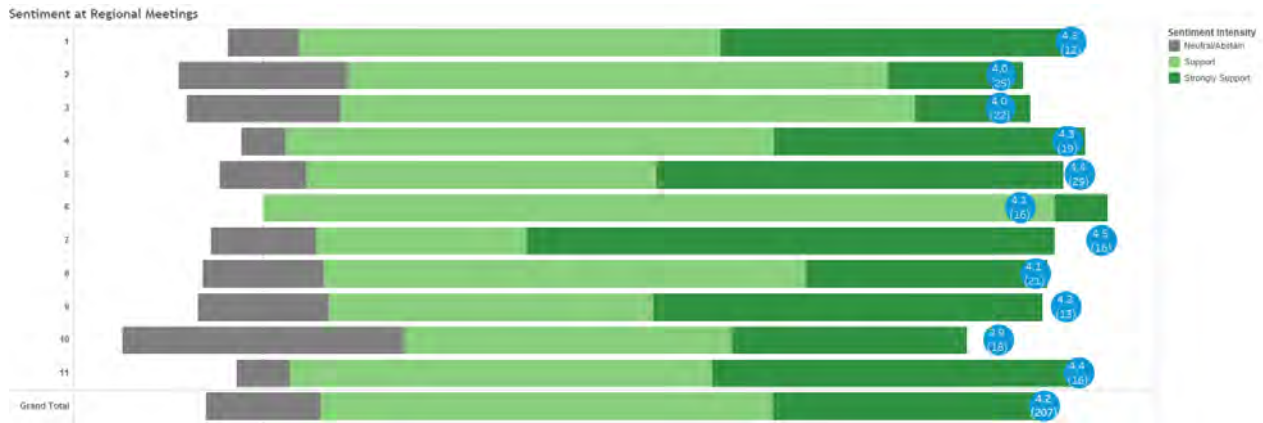
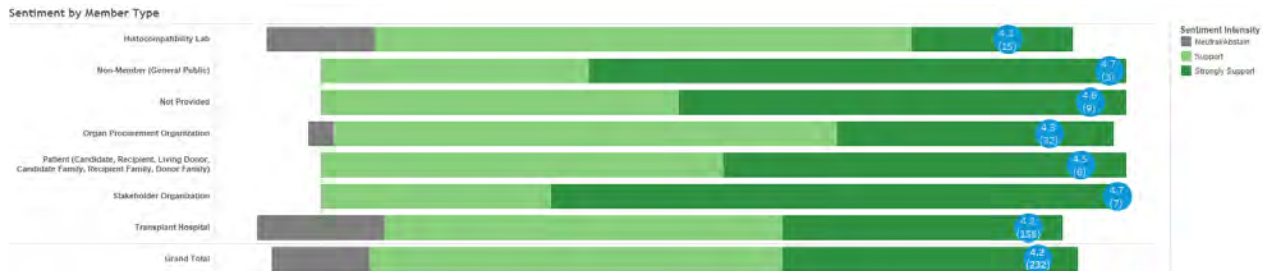


Figure 4 identifies sentiment support by OPTN member type. Similarly to the previous figure, there were no votes opposing or strongly opposing the proposal. Sentiment votes cast on behalf of transplant hospitals comprised approximately 70 percent of the total. Of the almost 160 sentiment votes cast by transplant hospital members, about 35 percent were strongly supportive of the proposal, another 49 percent were supportive, and the remaining 16 percent were neutral or abstentions. OPOs accounted for the next most votes by member type, and sentiment voting on behalf of those organizations was around 97 percent in support of the proposal.

Figure 4: Sentiment Support for the Proposal, by Member Type



Four professional organizations submitted written comments (**Table 3**). The American Society of Transplant Surgeons (ASTS), AST, NATCO, and the Society of Pediatric Liver Transplantation provided written support.

Table 3: Support for the Proposal, by Professional Organization²³

Organization	Response	Comments
American Society of Transplant Surgeons	Support	Support for proposal, but concerned that the creation of national boards may have unintended consequences and reduce innovation and exploration of new indications in transplantation
American Society of Transplantation	Support	Raised concern about potential workload increases for reviewers. Suggestions included including pediatric heart transplant size as a factor in how reviewers are randomly selected
Organization for Transplant Professionals	Support	Recommended including pediatric transplant program size and geography as factors in how reviewers are randomly selected
Society of Pediatric Liver Transplantation	Support	Suggested on-going evaluations of regional variation in decisions, and of waiting list and post-transplant mortalities

Significant support for creating a pediatric-specific heart review board was the dominant theme from the public comment period. There was less feedback addressing the specific operations of the board, such as its composition, as well as the voting and appeals processes. The themes are discussed in more detail.

Theme 1: Support for Creating a National Heart Review Board for Pediatrics Comprised of Reviewers With Pediatric Heart Expertise

There was widespread agreement among public comment participants that a pediatric-specific review board is needed. As mentioned, there was very strong support for creating such a board across the regional meetings. Likewise, written comments submitted to the OPTN website were very supportive of the proposal in general. Several comments stressed how important it is for pediatric heart professionals to make these decisions due to the uniqueness of pediatric candidates.

Concern that the reviewers lack the necessary level of experience to adequately evaluate pediatric heart cases was often cited among those supporting the creation of a pediatric-specific review board. The concern was expressed by non-professionals and professionals alike. Among those supporting the view were adult heart transplantation professionals who have experience serving on a heart review board. Many of them indicated that their expertise is limited regarding the management of pediatric heart issues. For instance, a respondent serving on a regional review board commented about not being especially qualified to address the intricacies associated with pediatric heart matters. As a result, the respondent found a review board comprised of pediatric heart transplant professionals to be a “highly desirable,” solution to the expertise issue.

Other comments suggested that the lack of expertise is a major reason why some many pediatric heart requests are approved by the review boards. Some of those submitting written comments indicated their belief that adult heart specialists who lack pediatric-specific experience are likely to approve an

²³ Public comments submitted to OPTN website. Accessed 04/03/2020. <https://optn.transplant.hrsa.gov/governance/public-comment/national-heart-review-board-for-pediatrics/>

exception request out of “compassion” for the candidates. Another comment acknowledged a tendency towards approving the requests regardless of the appropriateness of the request.

Among the comments supporting creation of the board, some recommended considering the National Liver Review Board (NLRB) as a resource in multiple ways. Members of the Pediatric Committee suggested the NLRB might be a helpful example during the early development of a national heart review board for pediatrics. Another comment urged maintaining consistency with the NLRB, where possible.

Theme 2: Overall Support for Composition of the NHRB for Pediatrics as Proposed, but Less Agreement Regarding What Criteria to Include With Randomization

The public comment proposal asked for feedback about the composition of the NHRB for Pediatrics. Specifically, the proposal document asked whether additional selection criteria should be included with the random selection of reviewers, Input was also requested regarding whether participation on the Board should be based on the volume of transplants completed, or whether it should be comprised on physicians only or surgeons only.

The general thrust of the comments appears to lie with ensuring all types of programs are equally represented on the board. While selecting reviewers at random for each case is well supported, there is less agreement concerning whether to also address geographic versus transplant volume factors. Several comments supported the adoption of criteria that would ensure geographic and transplant volume as part of the random selection of reviewers for each case. For example, some supported random selection based on OPTN region, while keeping the board size at nine. At least one comment questioned whether pediatric transplant programs in lower density areas would be under-represented if all programs are allowed equal participation. Others recommended giving greater weight in the selection process to programs that complete more transplants. Based on the comments received there was no consensus regarding the additional criteria to consider as part of the random selection process. For instance, some members of the Pediatric Committee supported the idea that larger programs should have more representation, while other members disagreed.

The Thoracic Committee did not include such restraints in the proposal that was released for public comment. As part of the proposal, they did request additional feedback on whether additional criteria should be considered along with the randomization of reviewer assignments. The Committee received feedback regarding different criteria that should be included. For example, comments submitted by the Organization for Transplant Professionals (NATCO) supported ensuring a geographic balance on the proposed board, as well as representatives from small and large centers.²⁴ The American Society of Transplantation’s (AST) public comment submittal recommended establishing a minimum threshold for pediatric heart cases for participation on the board. Based on the community’s input and their own expertise, the Committee decided to include pediatric transplant program size as an additional criterion.²⁵

²⁴ OPTN, Public Comment webpage, National Heart Review Board for Pediatrics, NATCO comment submitted on March 23, 2020 and AST comment submitted on March 23, 2020, <https://optn.transplant.hrsa.gov/governance/public-comment/national-heart-review-board-for-pediatrics/> (accessed on April 24, 2020).

²⁵ OPTN Thoracic Organ Transplantation Committee, Pediatric-Heart Workgroup, Meeting Summary, April 7, 2020.

Reviewers were also asked to comment on whether the board should have a chair, and if so, would a two-year term be appropriate, and what would be the selection process and responsibilities? Four comments addressed the question, with all four supporting the idea. Comments disagreed about how the chair would be chosen. One recommendation was for the Thoracic Committee to choose the chair, while another recommended that the chair not be from one of the pediatric programs.

Submitted comments supported a board comprised of physicians and/or surgeons, without strong support for one over the other. A comment suggested physicians might be more appropriate because of the amount of time surgeons will be in surgery.

Theme 3: Support for Proposed Voting Process, but Some Question Voting Timeframe

In developing the public comment proposal, the Thoracic Committee determined that reviewers should be expected to vote within three calendar days after being assigned a case. The Committee based this on high medical urgency of Status 1A and Status 1B pediatric candidates. Additionally, the number of pediatric exception requests each year is low compared to adult heart exception requests. During calendar year 2019, approximately 410 pediatric exception requests were assigned to the Heart regional review boards, while more than 3,000 adult exception requests were.

The public comment proposal asked members to consider whether three days is the right length of time to vote. Similarly to some of the questions about board composition, there were mixed responses regarding the voting time. Two of the written comments, including AST's, indicated three days was the correct time to review and vote. At the same time, two other written comments suggested that three days may not be enough time. It was noted that programs with fewer physicians may not be able to meet the deadline. The comment continued that because reviewers could be removed from the board for missing three decisions, providing adequate time is important.

Still, others found three days to be too long. Region 2 meeting participants expressed in reducing the voting time to two calendar days. While at the Region 5 meeting, a participant recommended changing the proposed approach from retrospective to prospective reviews, and requiring Status 1A exception requests be completed within 24 hours, and Status 1B requests be completed within three days.

The proposal also establishes guidelines for the appeals process. Appeals are assigned to the same group of nine reviewers who reviewed the denied exception request. If the appeal is not approved, the heart transplant program may initiate a final appeal to the Thoracic Committee. According to the operational guidelines in the proposal, the Thoracic Committee may delegate review of such appeals to a five-member workgroup comprised of members from the Thoracic Committee, Pediatric Committee, or other pediatric heart physicians or surgeons.

Few responses addressed the five-member workgroup that would review the final appeal, suggesting agreement with the proposed composition. The proposal specifically asked for feedback on whether a member of the appeal workgroup should be allowed to participate in the final appeal if that individual had participated in any of the earlier reviews. Three of the four written comments addressing the matter supported allowing that to occur. Of the four, AST supported the idea, while NATCO recommended using a new set of reviewers in order to present a true re-evaluation of the case.

Theme 4: No Consensus Whether a National Heart Review Board for Adults Should Be Created, But Some Comments About the NHRB for Pediatrics Reviewing Adult CHD Cases

The public comment proposal asked for feedback about using a national review board to review adult exception request. Creation of a national heart review board to address adult heart issues has been discussed in the past. While some in the heart community have supported the idea, others have not citing a desire to provide adequate monitoring to occur following the modifications to adult heart policy implemented in October 2018 and the elimination of donor service areas from policy as in January 2020. However, given the nature of the proposal, it was considered to be an appropriate opportunity to ask the community about it again.

Only a few comments addressed the question. The question was discussed during the Region 4 meeting, but there was not consensus on whether to expand the NHRB to adult cases. Region 2 attendees expressed an interest in seeing what lessons might be applicable to adult exception cases. However, there was a general consensus that a national heart review board for adults would be confronted with an overwhelming number of cases and may not be viable. Two comments were submitted that addressed potentially routing exception requests for adults with CHD through the NHRB due to the fact that adults with CHD have different issues than the rest of the adult candidates. Another written comment suggested that routing adult CHD candidate's exceptions through the NHRB for pediatrics has the potential to significantly increase the new board's workload. During the Region 7 meeting, it was requested that the NHRB for pediatrics not be responsible for reviewing adult CHD exception requests.

First, the Pediatric-Heart Workgroup reviewed and discussed the results of public comment. The Workgroup was also briefed on potential operational changes that might be necessary to implement the review board's activities in UNetSM. The members considered both the feedback received during public comment and the programming requirements, and made some changes to the operational guidelines for the NHRB for Pediatrics. The Workgroup's recommendations were presented to the full Thoracic Committee. The Committee reviewed the recommendations and concluded it was appropriate to submit the proposal as revised to the Board of Directors.

Proposal for Board Consideration

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.

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.

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 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 in the proposal that was released for public comment.

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 to the OPTN 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,²⁶ and the number of exceptions each year is not large²⁷, 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 two 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 reviewed retrospectively because these cases are so urgent that the candidates are awarded the status

²⁶ 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.

²⁷ 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.

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 may ultimately be denied, resulting in disadvantage to other candidates in that status.

If the reviewer does not vote within the allotted three days, and the matter has not been resolved, the case will be reassigned to another randomly selected reviewer from the pool of remaining pediatric heart transplant programs

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.

Currently, the voting process is not fully automated, and managed by OPTN staff. Under the new process voting will occur in UNetSM. A new system to review and record exception request votes will be created in UNetSM 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. The appeal request will be decided based on the majority vote by the reviewers, similarly to the process used for voting on the initial exception application. 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 has 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 Thoracic 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.

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 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.

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.

OPTN Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”²⁸

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

This proposal:

- **Is based on sound medical judgment**²⁹ because it is an evidenced-based change, relying on medical judgment 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.
- **Seeks to achieve the best use of donated organs**³⁰ by allocating and transplanting them for the most medically urgent pediatric heart candidates first.
- **Is designed to...promote patient access to transplantation**³¹ by assigning review of pediatric heart candidates’ 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.
- **Is not based on the candidate’s place of residence or place of listing, except to the extent required by [the criteria above]**³² by removing the consideration of place of listing from determining which review board will review the candidate’s Status exception request. For the proposed policy, removing consideration of a candidate’s place of listing will result in more equitable access to transplant because exception cases for pediatric candidates nationwide will be reviewed similarly, which in turn should result in candidates with comparable medical urgency qualifying for similar statuses.

²⁸ 42 CFR §121.4(a)(1)

²⁹ 42 CFR §121.8(a)(1).

³⁰ 42 CFR §121.8(a)(2)

³¹ 42 CFR §121.8(a)(5)

³² 42 CFR §121.8(a)(8)

The national board would seek to minimize local differences and improve consistency. The improvements will better align with the Final Rule’s performance goal of ranking patients from most to least medically urgent by clarifying the circumstances under which it is appropriate to use and approve exceptions to the standard criteria.³³ Such clarifications will help ensure hearts are provided to the sickest pediatric candidates first.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,³⁴ and it is specific to an organ type, in this case hearts.³⁵

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

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

The Final Rule also requires the OPTN to “**consider whether to adopt transition procedures” to ensure individuals on the waiting list or awaiting transplant prior to the adoption or effective date of a revised policy are not treated less favorably under the revised policy than such individuals would have been treated under the previous policy.**”³⁶ The Workgroup considered whether pediatric heart candidates at status 1A by exception might be a population treated less favorably following implementation of the NHRB for Pediatrics.³⁷ The Workgroup stated that an objective of the proposal is to have professionals with expertise in pediatric heart transplantation be responsible for reviewing pediatric heart exception requests. By more closely aligning the circumstances of the pediatric candidates for whom exception requests are submitted with the experience of those who treat them, the Workgroup concluded that the increased specialization would put all pediatric heart candidates in the most appropriate clinical classification, and; therefore, decided not to recommend a transition procedure.

Alignment with OPTN Strategic Plan³⁸

1. *Improve equity in access to transplants:* The proposal seeks to mitigate regional variation in the evaluation and approval of pediatric heart exception requests by establishing a single, national board comprised of pediatric heart specialists.
2. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The proposal seeks to clarify the circumstances under which it is appropriate to use and approve exceptions to the standard pediatric heart criteria established in policy. Such clarifications will help ensure pediatric hearts are provided to the sickest candidates first.

³³ 42 CFR §121.8(b)(2)

³⁴ 42 CFR §121.8(a)(3)

³⁵ 42 CFR §121.8(a)(4)

³⁶ 42 CFR §121.8(d)(1)

³⁷ OPTN, Pediatric-Heart Workgroup of the Thoracic Transplantation Committee, Meeting summary, April 29, 2020.

³⁸ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

Implementation Considerations

Member and OPTN Operations

The proposal is expected to involve substantial implementation efforts by the OPTN related to system development and reporting in UNetSM. Transplant programs will also be impacted by the introduction of a new process for resolving exception requests.

Operations affecting the OPTN

This proposal will require programming in UNetSM. The bulk of this effort will involve integrating the current processes used on behalf of the Heart regional review boards for collecting, storing, and sharing information within UNetSM. Another integration effort will involve the exchange of exception-related information. OPTN staff currently copy information from the Heart justification forms as submitted by the transplant programs and paste it into another document in order to share it with review board members. Replacing existing processes such as this one, and developing a similar, but new, process within UNetSM will require programming time, but will also result in a more efficient process with which to share the information. The OPTN will be responsible for setting up the operating structure, including case assignments and criteria, developing new justification forms, and onboarding reviewers. The OPTN will also create educational materials to help with orientation of NHRB members in their role as reviewers.

Operations affecting Transplant Hospitals

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.

Changes to the justification forms for pediatric exception request and the voting process may require pediatric heart transplant programs to revise their training efforts in order to accommodate the switch to UNetSM.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of Histocompatibility Laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of the Organ Procurement Organizations.

Projected Fiscal Impact

Projected Impact on the OPTN

Policy and Community Relations and IT staff supported a joint Pediatric and Thoracic workgroup to design the processes for the NHRB for Pediatrics that largely mirror the existing National Liver Review Board (NLRB) and create a streamlined Review Board system in UNetSM.

The NHRB for Pediatrics is estimated as a very large effort. By comparison, the original cost estimates established for the NLRB, a similar review board, were projected as an enterprise level effort. The Workgroup achieved efficiencies and lower implementation costs by recommending an approach aligned with the structure of the NLRB and UNetSM Review Board system. By following the NLRB and UNetSM Review Board patterns, the chosen design for NHRB for Pediatrics will result in large savings related to programming costs. The OPTN will recognize cost savings from using previously determined and developed patterns for handling appeals, user interface (UI) and user experience (UX) needs, reporting, handling “out-of-the-office” needs, workflow, and testing of existing functionality.

Current functionality for all Heart regional review board needs exists in REDCap, a secure web application for building and managing online surveys. As previously discussed, the current voting process is not fully automated, and is managed by OPTN staff. The Workgroup realized the importance of standardizing review board operations across organs and; therefore, chose to approach the NHRB for Pediatrics on a way that is structurally similar to the NLRB. By moving to UNetSM, and away from REDCap, the project reduces potential user error, and the workload on review board staff, as well as streamlines functionality for transplant center staff.

The current estimated costs are based on replicating NLRB functionality for the processes identified to support the NHRB for Pediatrics. The changes will be associated with the need to create a landing page specific to the NHRB for Pediatrics, voting views, updates to all justification forms so that they can display in UNetSM to review board members and review board staff, a pattern to build out the system in a way that can be utilized by adult heart if needed in the future, and necessary testing.

Projected Impact on Transplant Hospitals

This proposal is anticipated to have minimal or no fiscal impact for Transplant Hospitals.

Projected Impact on Histocompatibility Laboratories

This proposal is anticipated to have minimal or no fiscal impact for Histocompatibility Laboratories.

Projected Impact on Organ Procurement Organizations

This proposal is anticipated to have minimal or no fiscal impact for Organ Procurement Organizations.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”³⁹

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

³⁹ 42 CFR §121.8(a)(7).

Policy Evaluation

The Final Rule requires allocation policies to be “reviewed periodically and revised as appropriate.”⁴⁰ 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 UNetSM) 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 exception reviews, reduce variation in the volume of transplants for Status 1A candidates by region, and reduce the variance in waiting list mortality within a status.

⁴⁰ 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.

3

4

Table 6-3: Exception Qualification and Periods

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1	<ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 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 	RRBs retrospectively review requests for status 1 exceptions	14 days	<ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively
Adult status 2	<ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 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 	RRBs retrospectively review requests for status 2 exceptions	14 days	<ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively

<p>Adult status 3</p>	<ol style="list-style-type: none"> 1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 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>RRBs retrospectively review requests for status 3 exceptions</p>	<p>14 days</p>	<ul style="list-style-type: none"> • Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
<p>Adult status 4</p>	<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>	<p>90 days</p>	<ul style="list-style-type: none"> • Require RRB approval for each successive 90 day period • RRB will review and decide extension requests retrospectively
<p>Pediatric status 1A</p>	<ul style="list-style-type: none"> • Candidate is admitted to the transplant hospital that registered the candidate on the waiting list • 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><u>The national heart review board (NHRB)</u> RRBs retrospectively reviews requests for Status 1A-exceptions</p>	<p>14 days</p>	<ul style="list-style-type: none"> • Require <u>The NHRB</u> approval for each successive 14 day period • <u>The NHRB RRB</u> will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned pediatric status 1B

Pediatric status 1B	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	The NHRB RRBs retrospectively reviews requests for Status 1B exceptions	Indefinite	<ul style="list-style-type: none"> • Not required as long as candidate’s medical condition remains the same
------------------------	--	---	------------	--

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 Heart
16 Transplantation Committee. If the Thoracic Heart Transplantation Committee agrees with the review
17 board’s RRB’s decision, then the Thoracic Heart Transplantation Committee may refer the case to
18 Membership & Professional Standards Committee (MPSC) for review according to *Appendix L* of the
19 OPTN Bylaws.
20

21 **6.4.A.i. Review Board RRB Appeals**

22 If the review board RRB denies an exception or extension request, the candidate’s
23 transplant program must either appeal to the relevant review board RRB within 1 day of
24 receiving notification of the review board RRB denial, or assign the candidate to the status
25 for which the candidate qualifies within 1 day of receiving notification of the review board
26 RRB denial.
27

28 **6.4.A.ii Committee Appeals**

29 If the review board RRB denies the appeal, the candidate’s transplant program must within
30 1 day of receiving notification of the denied appeal either appeal to the Thoracic Organ
31 Heart Transplantation Committee or assign the candidate to the status for which the
32 candidate qualifies. If the Thoracic Heart Transplantation Committee agrees with the review
33 board’s RRB’s decision, the candidate’s transplant program must assign the candidate to the
34 status for which the candidate qualifies within 1 day of receiving notification of the denied
35 Committee appeal. If the transplant program does not assign the candidate to the status for
36 which the candidate qualifies within 1 day of receiving notification of the denied Committee
37 appeal, then the Committee will refer the case to the MPSC.
38

Operational Guidelines Language

National Heart Review Board for 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 exception application, extension exception applications, and appeals.

Representation

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

Primary and alternate representatives serve one-year terms. A pediatric heart transplant program may appoint the same primary and/or alternate representative 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 heart component.

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

Responsibilities of Primary and Alternate Representatives

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

Representatives must vote within 3 days on all initial exception applications, exception extension applications, and appeals. On day 4, if the vote has not been completed, then the application will be randomly reassigned to another representative. The original reviewer will receive a notification that the application has been reassigned.

Primary representatives must notify UNOS in advance of absences, during which the alternate will fulfill the responsibilities of the representative.

41 If a primary or alternate representative does not vote on an open application within 3 days on 3
 42 separate instances within a 12 month period, the Chair of the Heart Transplantation Committee (Chair)
 43 may remove the individual from the NHRB. If a representative or alternate does not vote because a case
 44 is approved and closed before the 3 day timeframe expires, it is not considered a failure to vote. A
 45 representative or alternate who has been removed for failure to perform the duties required is not
 46 eligible to serve again for 3 years.

47
 48 If a pediatric heart transplant program exhibits a pattern of non-responsiveness, as evidenced by the
 49 removal of 2 members from the NHRB, the Chair may suspend the program’s participation for a period
 50 of 3 months after notifying the program director. Further non-compliance with the review board process
 51 may result in cessation of the program’s representation on the NHRB until such a time as the transplant
 52 program can satisfactorily assure the Chair that it has addressed the causes of non-compliance.

54 Voting Procedure

55 Each initial exception application is assigned retrospectively to a randomly generated group of nine
 56 representatives of the NHRB. The random selection process will include a metric for program size as an
 57 additional selection criterion. Program size will be re-calculated at least annually. A representative may
 58 vote to approve or deny the application, or ask that the application be reassigned. The NHRB will
 59 retrospectively review extension exception applications. Each extension exception application is
 60 assigned to the same group of nine representatives who reviewed the initial exception application.

61
 62 Voting will close at the earliest of when:

- 63 • 5 reviewers have voted to approve an application;
- 64 • 5 reviewers have voted to deny an application; or
- 65 • 6 days after the first reviewer received the application

66
 67 When voting is closed, NHRB review of applications is decided as described in Table 1, below:

68
 69 **Table 1: Effect of NHRB Votes**

<u>Of the votes submitted, if...</u>	<u>Then the application is...</u>
<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>

70
 71 Representatives no longer have the ability to vote after voting is closed.

72 73 Appeal Process

74 A pediatric heart transplant program may appeal the NHRB decision to deny an exception application.
 75 Patients are not eligible to appeal exception applications. All reviewer comments are available in UNetSM.
 76 The NHRB advises programs to respond to the comments of dissenting reviewers in the appeal.

77
 78 Each appeal is assigned to the same group of nine representatives who reviewed the initial exception
 79 application. A representative may vote to approve or deny the application, or ask that the application be
 80 reassigned.

81
82 Voting will close at the earliest of when:

- 83 • 5 reviewers have voted to approve an application;
- 84 • 5 reviewers have voted to deny an application; or
- 85 • 6 days after the first reviewer received the application

86
87 When voting is closed, NHRB review of appeals is decided as described in Table 2, below:

88
89 **Table 2: Effect of NHRB Appeal Votes**

<u>Of the votes submitted, if...</u>	<u>Then the appeal is...</u>
<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>

90
91 If the appeal is denied, the pediatric heart transplant program may initiate a final appeal to the Heart
92 Transplantation Committee (Heart Committee).

93
94 If an initial exception application will expire before the deadline for the NHRB for Pediatrics or the NHRB
95 for Pediatrics Appeals Workgroup to decide on the application, and the transplant program submits an
96 application for an extension of that application, then the extension exception application will be put on
97 hold until the appeal of the initial exception application has been resolved. If the appeal of the original
98 exception application is resolved in favor of the pediatric heart transplant program’s request, then the
99 extension exception application will be released and assigned to the same group of nine representatives
100 who reviewed the initial exception application. If the appeal of the original exception application is
101 resolved against the pediatric heart transplant program, then the extension exception application will
102 not be eligible for review and thus, not approved.

103
104 **Appeals to the Heart Transplantation Committee**

105 The Heart Committee may delegate review of appeals to a NHRB for Pediatrics Appeals Workgroup of at
106 least five members which may consist of members of the Heart Committee, Pediatric Committee, or
107 other pediatric heart physicians or surgeons.

108
109 If the appeal achieves a majority of affirmative votes, it will be approved. In the event of a tie, the
110 appeal will be approved. If either the program or a representative requests that the appeal be
111 considered on a conference call, then a call will be scheduled with the NHRB for Pediatrics Appeals
112 Workgroup.

113
114 #

115

OPTN Adult Heart Regional Review Board (HRB RRB)

Operational Guidelines

1. Overview

The purpose of the Adult Heart Regional Review Board (HRB RRB) 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 RRB. Each HRB RRB 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 RRB Chair. The HRB RRB Chair will be called upon to decide tie votes and may not simultaneously represent his or her transplant program as an HRB RRB member.
- C. The HRBs RRBs vary in size and rotate as determined by each OPTN region. Since larger HRBs RRBs may pose operational or administrative challenges, some HRBs RRBs rotate membership to ensure each transplant program is represented on the HRB RRB for one term each year.
- D. Each program represented on the HRB RRB 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 RRB primary and alternate representatives. Should an HRB RRB primary representative leave his or her transplant program, then the transplant program’s alternate representative will become the new HRB RRB 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 RRB primary representative.
- E. If a transplant hospital inactivates or withdraws its heart program, it may not participate in the HRB RRB. The term of the transplant program’s representative on the HRB RRB 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 RRB representatives

HRB RRB primary and alternate representatives must:

- 45 A. Complete the OPTN/UNOS Confidentiality Agreement and Certification Regarding Conflicts of
46 Interest form prior to serving on the HRB RRB.
- 47 B. Evaluate the eligibility criteria of other approved applications to achieve consistency in
48 decision-making and determine whether this candidate meets similar levels of medical
49 urgency and potential for benefit.
- 50 C. Vote to approve or not approve applications according to the timelines specified in the
51 guidelines below. When voting to “not approve” an application, the voter should provide
52 comments or questions to the program submitting the application to support the vote.
53

54 4. Voting Procedures

55 A. Retrospective Review of Status Exceptions

56 The HRB RRB will review all applications that require HRB RRB review retrospectively. During the
57 entirety of the retrospective review, extension, and/or appeal process, the candidate’s status will be
58 equal to the requested status and the transplant program must follow all OPTN policies applicable to
59 the requested status.
60
61

62 At the termination of the application or appeal process, if the requested status is not approved, then
63 the transplant program must change the candidate’s status to the status for which the candidate
64 qualifies under policy within 1 day of receiving notification of denial or initiate an appeal as described
65 below.
66

67 B. Eligibility to Vote

68 An HRB RRB primary or alternate representative’s vote will not be valid and will not count towards a
69 quorum in any case in which the member has a conflict of interest.
70
71

72 C. Regional Rotation

73 The HRB RRB will review applications from another OPTN region on a rotating basis. The same HRB
74 RRB that reviewed an initial application will review extension requests and appeals associated with
75 the candidate, with the exception of applications that are extended or appealed after the regional
76 rotation to different regions occurs.
77

78 D. HRB RRB Case Review and Vote

79 ~~The OPTN Contractor will first send all applications~~All applications will first be sent to the HRB RRB
80 primary representative. If the primary representative has not voted within 3 business days ~~of when~~
81 ~~the OPTN Contractor sends the application to the HRB~~of the HRB RRB receiving the application, then
82 ~~the OPTN Contractor will send the case~~will be sent to the alternate representative. Thereafter, both
83 the HRB RRB member and alternate representative may vote on the application within 7 days of when
84 the ~~OPTN Contractor originally sent the application~~application was originally provided to the HRB
85 RRB. If the HRB RRB member and the alternate representative both submit votes for the same
86 application, then the OPTN Contractor will count the vote from whomever voted first will be counted.
87
88
89

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

Voting will close at the earliest of when:

- all eligible voters have voted;
- a majority of all eligible voters have voted to approve ~~or deny~~ a request
- a majority of all eligible voters have voted to deny a request; or
- 7 days after the ~~OPTN Contractor sends the request is sent~~ to the HRB RRB

HRB RRB review of applications (initial submissions, extensions, and appeals) are decided as described in Table 1, below:

Table 1: Effect of HRB RRB Votes

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

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

The ~~OPTN Contractor~~ will maintain the results of the HRB's RRB's vote. If an application is not approved, the ~~OPTN Contractor~~ will notify the program that submitted the application and will provide the transplant program with comments or questions made by the HRB RRB members, but will not provide the votes of specific HRB RRB members.

5. Appeal Process

A. Appeal to the Review Board

If the HRB RRB does not approve an initial or extension request application, the candidate's transplant program must either submit an appeal application to the HRB RRB within 1 day of receiving notification of the HRB RRB decision, or assign the candidate to the status for which the candidate qualifies within 1 day of notification of the HRB's RRB's decision.

The transplant program may submit additional written information justifying the requested exception status, and may include responses to the comments of dissenting HRB RRB members. This additional information will be provided to HRB RRB members for further consideration.

124
125 If the application is not appealed to the HRB RRB within 1 day of receiving the notification of the
126 HRB's RRB decision, the appeal process is not available.

127
128 Appealed applications are adjudicated as described in **Table 1**, above.

129
130 **B. Appeals of HRB RRB Denials to the Thoracic Heart Transplantation Committee and MPSC Review**

131
132 If the HRB RRB denies the appeal of an initial application or extension request application, the
133 candidate's transplant program must either appeal to the Thoracic Organ Heart Transplantation
134 Committee (Committee) within ± one day of receiving notification of the denied appeal or assign the
135 candidate to the status for which the candidate qualifies within 1 day of notification of the denied
136 appeal.

137
138 The transplant program may provide the OPTN ~~Contractor~~ with additional information about the
139 case, which the OPTN ~~Contractor~~ will send to the Committee. The Committee will approve or not
140 approve each appeal within 7 days of submission of the case to the Committee.

141
142 Referral of cases to the Committee will include information about the number of previous case
143 referrals from that transplant program and the outcome of those referrals.

144
145 If the application is not appealed to the Thoracic Heart Transplantation Committee within one day of
146 receiving the notification of the HRB RRB decision, the appeal process is not available.

147

148 6. Extensions

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

153

154 7. Administration

155 The central office for each HRB RRB is maintained by the OPTN ~~Contractor~~. The HRB RRB efforts are
156 coordinated by the OPTN ~~Contractor~~.

157

158 Data sent to the HRBs RRBs for action or review will not contain hospital, program, or candidate
159 identifying information.

160

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

163

164 #

Appendix A: Pediatric Heart Transplants by Region, Exception Status, and Timeframe Associated With Policy Changes Implemented in March, 2016⁴¹

Status and Policy Implementation Period	1	2	3	4	5	6	7	8	9	10	11	Total
1A – Exceptions												
Pre (03/22/2015 – 03/21/2016)	1	1	4	2	3	1	2	2	0	1	1	18
Transition (03/22/2016 – 09/30/2016)	0	3	3	1	6	1	7	2	4	3	2	32
Post (10/01/2016 – 12/31/2017)	0	3	18	2	7	1	6	5	4	7	9	62
1B – Exceptions												
Pre	0	0	4	3	0	1	1	0	1	0	1	11
Transition	1	1	5	3	7	0	2	0	0	0	1	20
Post	0	2	3	2	8	3	1	2	0	1	3	25
Status 2												
Pre	1	3	0	0	3	0	0	0	0	2	1	10
Transition	0	0	1	0	2	0	0	0	1	1	1	6
Post	3	1	1	4	5	2	0	0	0	1	1	18
Status 1A – Meeting Criteria												
Pre	14	20	49	17	39	10	25	31	26	28	30	289
Transition	5	13	31	12	23	5	12	15	7	9	19	151
Post	8	29	47	38	53	10	37	30	28	33	48	361
Status 1B – Meeting Criteria/Auto Downgrade												
Pre	1	0	0	5	7	2	0	1	1	0	1	18
Transition	0	1	4	5	9	1	2	5	2	2	1	32
Post	1	2	9	5	11	0	7	11	3	7	7	63

⁴¹ OPTN, Final Report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 9, 2018, pp. 15-17.