Proposal to Modify the Adult Heart Allocation System

OPTN/UNOS Thoracic Organ Transplantation Committee

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Affected Policies:	*Policy 3.7.B: Required Expedited Modifications of Waiting Time, Policy 6.1: Status Assignments and Update Requirements, Policy 6.1.A: Adult Heart Status 1A Requirements, Policy 6.1.B: Adult Heart Status 1B Requirements, Policy 6.1.C: Adult Heart Status 2 Requirements, Policy 6.2: Status Updates, Policy 6.3: Adult and Pediatric Status Exceptions; Policy 6.3.A: RRB and Committee Review of Exceptions, Policy 6.3.B: Exceptions to Allocation for Sensitized Candidates, Policy 6.4: Waiting Time, Policy 6.5.C: Sorting Within Each Classification, Policy 6.5.D: Allocation of Hearts from Donors at Least 18 years Old, Policy 6.5.E: Allocation of Hearts from Donors Less Than 18 Years Old, and Policy 6.5.F: Allocation of Heart-Lungs*
Sponsoring Committee:	*Thoracic Organ Transplantation*
Public Comment Period:	*August 15, 2016 – October 15, 2016*

Executive Summary

The Thoracic Organ Transplantation Committee (the Committee) proposes modifications to the adult heart allocation system to better stratify the most medically urgent heart transplant candidates, reflect the increased use of mechanical circulatory support devices (MCSD) and increased prevalence of MCSD complications, and address geographic disparities in access to donors among heart transplant candidates. In response to significant comments received during the first round of public comment (**Exhibit A**), and based on additional feedback provided and consensus-building that occurred after that public comment cycle, the Committee proposes the following modifications to the original proposal:

- Refining and tightening the qualifying criteria for candidates supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO), percutaneous circulatory support devices, intra-aortic balloon pumps (IABP), and multiple inotropes to require evidence that these candidates are supported by these therapies for treatment for cardiogenic shock, rather than qualifying based on the presence of the therapy alone
    - Criteria for determining presence of cardiogenic shock are based on American Heart Association definitions or the presence of end-organ dysfunction
- Placing additional restrictions on the duration that candidates may remain in statuses 1 through 3
    - Candidates supported by the therapies above, which are intended for short-term, acute therapy for cardiogenic shock, will be limited to 14 days in the respective status unless the candidate exhibits contraindications to use of a durable device and has failed a weaning attempt. Candidates supported by VA ECMO are further limited to 7 days in status 1.
- Clarifying which mechanical circulatory support devices qualify a candidate for certain statuses, including limiting status 1 to candidates supported for biventricular failure with surgically-implanted, non-endovascular devices
- Requiring regional review boards to review cases external to their region
- Limiting the proposed broader geographic sharing scheme for the most urgent candidates to donation service area and Zone A (instead of through Zone B)
- Modifying the pediatric donor allocation sequence to limit potential negative impacts of the new adult heart allocation system on pediatric candidates

What problem will this proposal solve?

Since the last significant revision to the adult heart allocation system in 2006, there has been an overall decline in waiting list mortality rates among adult heart transplant candidates, and specific patient groups intended to benefit from the previous policy changes experienced the most substantial decline in mortality rates. The Committee acknowledged the success of the 2006 policy modifications, but ultimately determined that there are candidate groups disadvantaged by the current system for various reasons, such as their diagnosis, the way their physician chooses to treat their condition, or because of geographic location. The Committee determined there are four major problems with the current system:

1) Too many candidates with disparate urgency risks in the most urgent status
2) Too many exception requests required
3) Current system does not accommodate increased use of MCSDs
4) Geographic sharing scheme is inequitable

Too Many Candidates in the Most Urgent Status

Since 2006, the number of active heart transplant candidates more than doubled from 1,203 candidates on July 31, 2006 to 3,008 candidates on November 30, 2015. During that same time period, the number of status 1A candidates increased 548 percent, from 58 to 376, and the number of status 1B candidates increased 580 percent, from 255 to 1,734. By 2015, sixty-seven percent of adult heart transplants (2,347) were performed for patients that were status 1A at time of transplant. Candidates classified as status 1A are three times more likely to die on the waiting list than candidates in any other status, and also have vastly disparate waiting list mortality risks even within status 1A. The current system therefore requires stratification that is more granular in order to ensure that candidates in most need have access to donor hearts first.

Too Many Exception Requests Required

Some candidate groups, such as candidates diagnosed with amyloidosis or congenital heart disease, are not served well by the current system and often must request exceptions. Between January 2014 and December 2015, members submitted 5,340 status 1A exceptions on behalf of 1,240 candidates and 538 status 1B exceptions on behalf of 326 candidates. Relying on exceptions is not optimal for the patient, because whether to submit an exception is a choice left to each transplant program which can lead to variability in practice, and exception requests must be approved by a regional review board, leading to the potential for variability dependent upon the region in which the request was made. The proposed policy better accounts for relative waiting list mortality rates of all candidate groups, including those candidates currently forced to apply for policy exceptions, and treats these patients more equitably.

Increased Use of MCSDs Not Accommodated by Current System

Medical practice in the heart transplant community has evolved since 2006; use of MCSDs has increased significantly, though disparately depending upon geography. In 2007, only 8.9 percent of candidates were first registered under an MCSD-related criterion; by 2015, that percentage increased to 24.4 percent (and 34.5 percent of status 1A or 1B registrations). Increased use of MCSDs has occurred concurrently with changes in available technology and broadening of the patient population being supported. The devices and patients vary widely in risk, based on the severity of heart failure, the requirement for biventricular support, the type of MCSD being implanted, and the occurrence of complications, none of which are included in current policy. The proposed system better stratifies candidates based on the type of MCSD support and the risks associated with specific device complications.

Geographic Sharing Scheme is Inequitable

In March 2000, the US Department of Health and Human Services (HHS) implemented the Final Rule, which instructs that OPTN/UNOS allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on the candidate's place of residence or place of listing except to the extent needed to satisfy other regulatory requirements.[1] The current geographic sharing scheme favors less urgent candidates in the local DSA rather than more urgent candidates who may be as close as 25 miles away from the donor but are in Zone A. The proposed policy modifies the current geographic sharing scheme to ensure the most urgent candidates have access to donors in a broader geographic area.

Why should you support this proposal?

The proposed policy addresses the problems outlined above by better distinguishing and prioritizing candidates based on urgency and by reflecting the conditions of a wider range of heart transplant candidates than the current system. The proposal incorporates physiological principles into criteria that were previously based on clinical consensus and subjective patient management decisions, and not clearly stated in policy. It also increases access to the donor pool for candidates most urgently in need of transplant. Most importantly, this proposal is expected to provide timely access to transplant for candidates most in need without negatively impacting candidates that may be able to wait longer for transplant.

This proposal also incorporates feedback from various stakeholders received during and after the first round of public comment in January 2016 (**Exhibit A**) and the second round of public comment in August 2016 (**Exhibit B**). To review feedback from different stakeholders and the Committee's response, see "**How was this proposal developed?"** below.

How was this proposal developed?

This proposal is four years in the making. The Committee followed a deliberate, evidence-based, consensus-building pathway to develop this proposal that included:

1. A review of the current allocation system and identification of its limitations
2. Identifying goals of modifications
3. Development of additional statuses
4. Development of broader sharing
5. Detailed definitions for status criteria
6. Additional policy clarifications

Review of Current Allocation System and Identification of its Limitations

The current adult heart allocation system stratifies active candidates into three medical urgency statuses: status 1A, status 1B, and status 2. Candidates are considered adults if they are registered on the waiting list at age 18 years or older. Candidates qualify for status 1A, if:

- they require continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes and continuous hemodynamic monitoring
- they are supported by a total artificial heart, an intra-aortic balloon pump (IABP), extracorporeal mechanical oxygenation (ECMO), mechanical ventilation, or a ventricular assist device (VAD) (for a 30 day discretionary period)
- they are implanted with a MCSD and are experiencing a device-related complication, or
- they have an approved exception

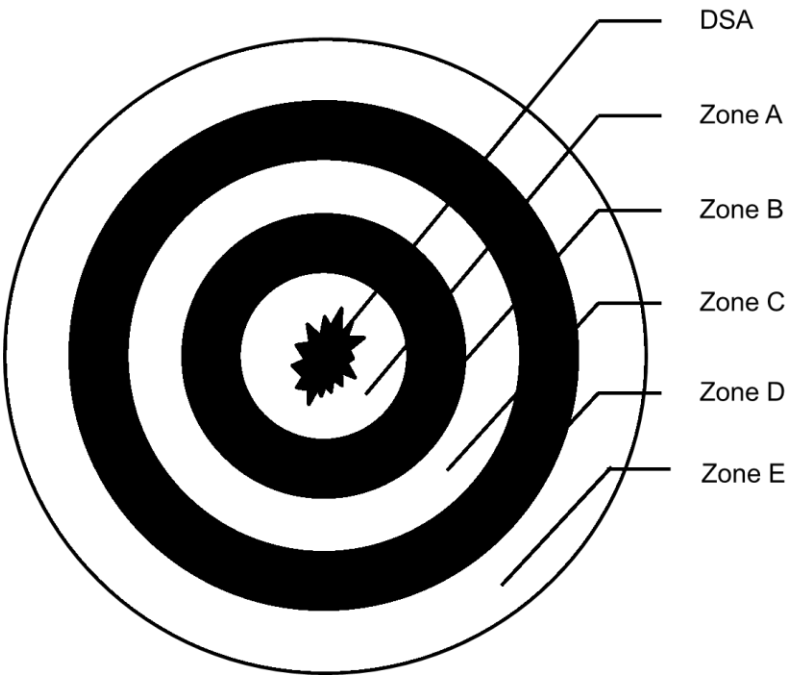
[1] 42 C.F.R. § 121.8

Candidates that are stable but supported by a VAD or that require continuous infusion of intravenous inotropes and do not meet the criteria for status 1A qualify for status 1B. Candidates that are in need of a heart transplant but do not meet status 1A or 1B qualifying criteria qualify for status 2.

Geographic allocation depends on the location of the donor. **Figure 1** demonstrates the zonal structure for allocation of thoracic organs. The donation service area (DSA) is the starting point, and is the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals. The 58 DSAs are not uniformly shaped and differ substantially in terms of land mass, area, population, and number of transplant programs.

Zone A includes all transplant hospitals within 500 miles of the donor hospital but outside of the donor hospital's DSA; Zone B includes all transplant hospitals within 1,000 miles of the donor hospital but outside of Zone A and the donor hospital's DSA; Zone C includes all transplant hospitals within 1,500 miles of the donor hospital but outside of Zone B and the donor hospital's DSA; Zone D includes all transplant hospitals within 2,500 miles of the donor hospital but outside of Zone C; and finally Zone E includes all transplant hospitals more than 2,500 miles from the donor hospital.

Figure 1: Zones Used for Thoracic Organ Allocation



In the current allocation system, organs recovered from deceased donors aged 18 years or older are first offered to status 1A candidates "locally" within the donor hospital's DSA and then to status 1B candidates locally. If not accepted locally, the heart is then offered to status 1A candidates in Zone A, and then to all status 1B candidates in Zone A. Only after offers are made through Zone A status 1B candidates is the heart then offered to a local status 2 candidate. Allocation then continues through subsequent geographic zones.

Identifying the Goals of Modifications

The Committee defined its goals in modifying the adult heart allocation system:

1. Reduce waiting list mortality rates
2. Reduce the use of exceptions to qualify for a status by better accommodating all candidate groups within the heart allocation system
3. Ensure that qualifying criteria for the statuses are based on objective physiological indications rather than therapeutic intervention
4. Improve overall access to transplantation in the heart allocation system by modifying geographic distribution to ensure maximum utility of donor hearts

To achieve the stated goals, the Committee debated three potential solutions:

1. Retain the current three-status system
2. Develop a heart allocation score
3. Develop additional statuses

The Committee considered retaining the current three-tiered system, but refining the qualifying criteria for each of the statuses. This idea was quickly dismissed because it is clear, based on the number of exception requests and disparate waiting list mortality rates for candidates in status 1A, that the adult heart candidate pool is too diverse to be stratified effectively by so few statuses.

In 2012, the OPTN/UNOS Board of Directors charged the Committee to "consider replacing the heart status system with a heart allocation score."[2] The Committee debated the merits of developing a heart allocation score (HAS). It acknowledged that a HAS ultimately may be the best method for accounting for post-transplant survival and net benefit. However, the OPTN does not currently collect all the data necessary to develop an appropriate HAS at this time. Based on these considerations, the Committee ultimately opted to develop additional statuses to better stratify heart transplant candidates while prospectively collecting additional data that may be necessary for developing a heart allocation score in the future, if the Committee decides to do so.

To plan for a heart allocation score, the Committee identified data that are likely to be predictive of waiting list mortality or post-transplant survival. These data are described in the "**Will this proposal require members to submit additional data?**" section below, as well as in **Exhibit C**.

Development of Additional Statuses

To develop additional statuses, the Committee first compared the waiting list mortality rates and post-transplant mortality rates of all heart candidates in each criterion, with a particular focus on better stratifying candidates currently in status 1A.[3]

The Committee reviewed data that revealed which candidates in status 1A currently have the highest waiting list mortality rates and the highest post-transplant mortality rates, and are transplanted most often. Moreover, waiting list mortality rates among status 1A candidates vary considerably by criteria. Six-month waitlist mortality among status 1A candidates varied from 4.8% in those with MCSD with infection, to 5.1% in those with VAD for 30 days, to 35.7% in those on VA ECMO. Status 1A candidates supported by mechanical ventilation and VA ECMO had the highest waiting list mortality rates, while candidates with continuous hemodynamic monitoring supported by multiple inotropes or a single high dose inotrope, VAD candidates using discretionary 30 day status 1A time, and MCSD candidates with infection exhibited the lowest waiting list mortality rates of the status 1A candidates.

The Committee also compared risk based on candidates' diagnoses at listing and at transplant within each urgency status. These data reveal that status 1A candidates have widely disparate waiting list

[2] 2012-2015 OPTN/UNOS Strategic Plan
[3] OPTN/UNOS Descriptive Data Request: "Outcomes for Adult Candidates and Recipients by Status 1A Criteria and Diagnosis." Prepared for Heart Subcommittee Conference Call, March 12, 2013.

mortality risks. Waiting list mortality and post-transplant survival rates currently vary based on medical urgency status, criteria, and sub-criteria, and by diagnosis stratified by status.

The Committee also analyzed all status 1A and status 1B exception requests submitted for heart and heart-lung candidates between July 2009 and June 2011 to identify common categories of exception requests (**Figures 2 and 3**).

Figure 2: Categories for Adult Status 1A Exception Narratives (N=640)

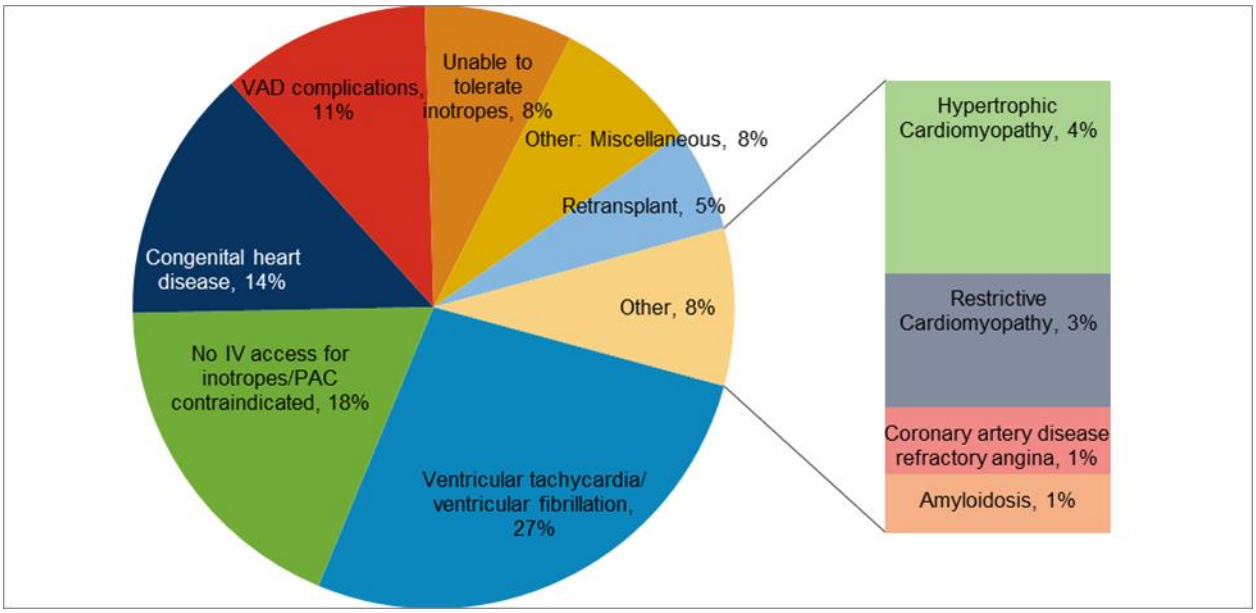
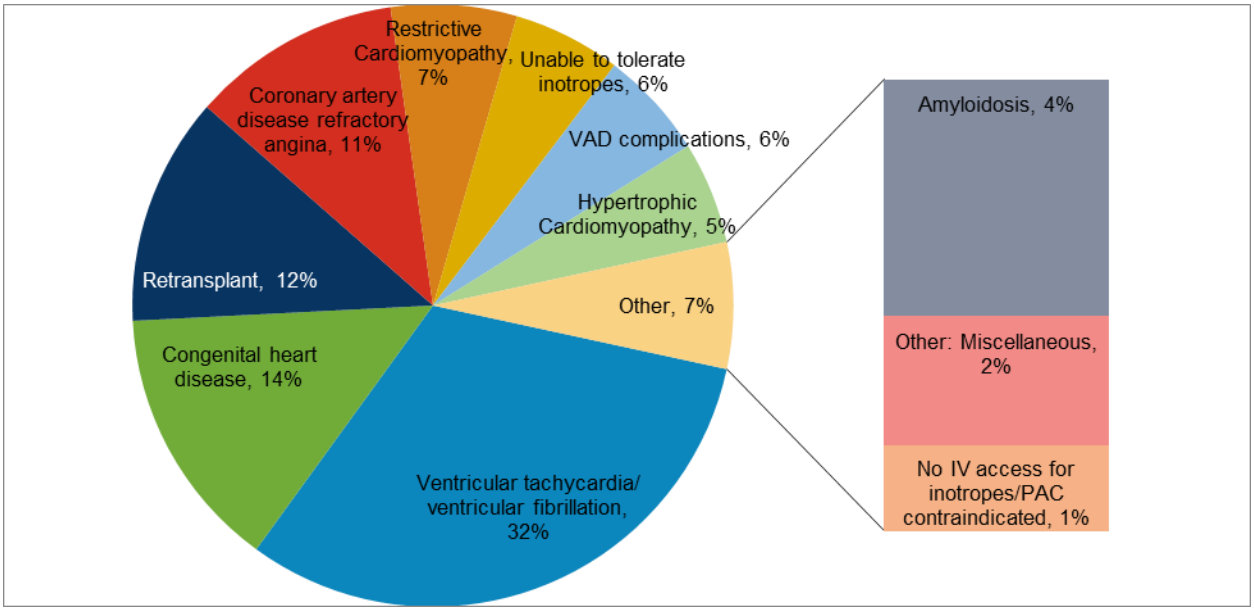


Figure 3: Categories for Adult Status 1B Exception Narratives



The three most frequently reported categories represent over half of the exception requests in both status 1A and status 1B. For status 1A, the most common rationale provided for exception requests were: 1) candidate is experiencing ventricular tachycardia or ventricular fibrillation; 2) candidate does not have intravenous access for inotropes or cannot tolerate a pulmonary artery catheter; and 3) congenital heart

disease diagnosis. For status 1B, the most common rationale provided for exceptions request were: 1) candidate is experiencing ventricular tachycardia or ventricular fibrillation; 2) congenital heart disease diagnosis; and 3) candidate requires a re-transplant.

After reviewing these data, the Committee formulated a draft, or "straw man," version of the proposed statuses. The straw man statuses primarily grouped candidates together by similar waiting list mortality rates, but also considered post-transplant mortality risk, as well as Committee members' experience with candidates in these groups.

After confirming the straw man groups, the Committee requested the SRTR perform a thoracic simulation allocation model (TSAM) to show the projected impact of the straw man statuses. The TSAM request was designed to mirror current allocation rules as closely as possible, including the intermingling of adult candidates and pediatric candidates, in order to verify that the modeled outcomes reflect the impact of the straw man itself, and not any other inadvertent changes to the allocation system. The results of this TSAM are described in the "**How well does this proposal address the problem statement?**" section below.

During the first round of public comment, some commenters expressed concern that by focusing on improving waiting list mortality rates, post-transplant outcomes may be negatively affected (**Exhibit A**). For example, candidates supported by VA ECMO have very high waiting list mortality rates, but also tend to do worse post-transplant. In the supporting evidence section below, **Figure 10** reveals that one-year post-transplant survival rates are not expected to increase significantly if the proposed changes are adopted. However, commenters expressed concern that the modeling is based on current behavior and practices, and that the proposal would influence practitioners to behave differently than they currently do; doctors may be more likely to put their patients on VA ECMO in the future if it means their patients are more likely to receive an organ offer more quickly. More patients transplanted after being supported by VA ECMO may mean that the overall system would experience worse post-transplant outcomes.

The Committee took these concerns seriously. Ultimately, the Committee re-committed to its primary goal of reducing waiting list mortality rates, particularly for the most urgent candidates, and made the decision to keep candidates stratified in the same order as the previous proposal as supported by data and TSAM. However, in weighing whether to defer to clinical expertise, or instead to adhere strictly to the models and data, the Committee determined that in matters of behavior, it should defer to clinical expertise. Therefore, the Committee reached out to the community to gain clinical consensus to guide the establishment of restrictions for the qualifying criteria for the most urgent statuses to attempt to avert unintended behavioral changes. The proposed restrictions are described in detail in the **"Detailed Definitions for Status Criteria"** below.

Development of Broader Sharing

Following a critical review of the TSAM data, the Committee was satisfied that patient subgroups were more accurately stratified and began considering improvements to the geographic sharing scheme. The Committee focused on an example that highlights a significant problem in the current system: if a donor heart becomes available in northern New Jersey, a status 1B heart candidate awaiting a heart transplant within the DSA in New Jersey would receive the organ offer before a status 1A candidate awaiting a heart transplant in Zone A in New York City, just 25 miles away.

The Committee believes allocating in this manner is not consistent with the Final Rule, which states that, to the extent feasible while not compromising patient health or the health of the donor organ, the OPTN's allocation policies "[s]hall not be based on the candidate's place of residence or place of listing…"

The Committee determined that broader sharing of adult hearts to the most urgent candidates first, as well as minimizing the impact of "local" sharing based on DSA, may help to ensure that the candidates most in need of transplant have access to the broadest range of available donors. The Committee debated which urgency statuses required the broadest sharing, as well as how far the first geographic

allocation unit should be. Ultimately, the Committee determined that proposed statuses 1 and 2 should benefit from the broadest sharing, as these candidates are very urgent and would benefit most from exposure to more donors. The number of candidates that will qualify for proposed status 1 and status 2 is also relatively small and therefore will have a smaller impact on candidates waiting in other statuses. For example, the TSAM results reveal that of the transplants performed under the originally proposed broader sharing scheme, 5 percent were status 1 candidates, 22 percent were status 2 candidates, 36 percent were status 3 candidates, and 30 percent were status 4 candidates. The Committee reaffirmed its commitment to providing broader sharing to status 1 and 2 candidates after the first round of public comment, and this principle was supported by the community during the post-public comment consensus gathering process.

The Committee debated whether to eliminate local sharing altogether, thereby implementing Zone A (500 miles from the donor hospital) as the first geographic unit of allocation. Some members of the Committee believe that local sharing is based on arbitrary boundaries. The Committee also recognized that some people reject the concept of minimizing or eliminating local sharing, asserting that people may be more willing to donate if they know their organs are going to be shared with their local community. However, there is no evidence to prove this assertion. Most people prefer their donated organs be allocated to the "more medically urgent patients regardless of where they live in the U.S."[4] One study noted "the public tends to draw community lines at national rather than local boundaries."[5] Moreover, many donors and donor families are not familiar with the DSA boundaries, and may also therefore be unaware that a DSA boundary may indeed run through their community, rather than circumvent it. Nevertheless, the Committee determined the best compromise is to keep local sharing as the first geographic unit of allocation, but to combine it with Zone A, so that all urgent candidates registered locally and within Zone A are grouped together, rather than sequentially.

The Committee also weighed the candidates' urgency against the safety of shipping organs further. If the first geographic unit were combined out to Zone B (1,000 miles from the donor hospital), then outcomes might be less optimal because more urgent candidates would be transplanted with organs with longer cold ischemic time. Additionally, it is more difficult to re-allocate an organ with more cold ischemic time in the event that the organ is not suitable for transplant for the particular patient for whom it was accepted. However, the Committee also acknowledged that an organ with a longer ischemic time might be appropriate for very urgent candidates. Additionally, hospitals concerned about travel time could deny the organ offer. As a compromise in the original proposal, the Committee determined that the most urgent candidates in the DSA and Zone A should have the first opportunity, *then* urgent candidates in Zone B.

During and after the first round of public comment, some members of the community expressed concerns that sharing to Zone B for the sickest patients may negatively affect post-transplant outcomes (**Exhibit A**). The TSAM results, modeling the potential impact of various broader sharing schemes described in the "**How well does this proposal address the problem statement?**" section below, do not support the assertion that post-transplant outcomes will be significantly worse if broader sharing is adopted. In response, the Committee reexamined the TSAM results and determined that there will still be substantial improvement in transplant rates for status 1 and 2 candidates even if geographic sharing for status 1 and 2 patients is limited to the DSA plus Zone A, which may in turn reduce the number of deaths on the waiting list. Therefore, in the revised proposal the Committee put forth that broader sharing should initially extend only to status 1 and 2 candidates in the DSA plus Zone A. Status 1 and 2 candidates in Zone B will receive offers only after status 3 candidates in the DSA. This compromise ensures that high urgency candidates in a reasonably broad geographic area have equitable access to organ offers, while

[4] National Survey - Organ Donation
[5] M. L. Volk, G. J. W. Warren, R. R. Anspach, M. P. Couper, R. M. Merion, P. A. Ubel. "Foreigners Traveling to the U.S. for Transplantation May adversely Affect Organ Donation: A National Survey." American Journal of Transplantation: 2010; 10: 1468-1472. DOI: 10.1111/j.1600-6143.2010.03111.x

minimizing the potential increase in donor organ ischemic times (and possible consequent worsening of post-transplant outcomes).

The Committee also realized that the pediatric donor sequence in the original proposal could negatively impact some pediatric patients, despite the Committee's intention to leave pediatric donor allocation largely unchanged. The goal of the original proposal was to minimize the impact, or provide a positive impact, on allocation of donor hearts to children. The primary mechanism for doing so was to equate status 1A pediatric candidates with status 1 adult candidates, status 1B pediatric candidates with status 3 adult candidates, and status 2 pediatric candidates with status 6 adult candidates. Consistent with current allocation policy, offers from pediatric heart donors would be made to pediatric candidates ahead of adult recipients at the equivalent status and in the same geographic range, while equivalent pediatric and adult candidates in the same geographic range would be grouped together for offers from adult heart donors. Because new status 1 adult candidates are the subset of current status 1A adult candidates with highest waitlist mortality, and new status 3 adult candidates are the subset of current status 1A adult candidates with the lowest waitlist mortality, the Committee believed this scheme would benefit pediatric candidates and increase the availability of both adult and pediatric donor hearts to pediatric candidates at both status 1A and 1B.

Despite these intentions, there was significant public comment received regarding the potential for a negative impact on allocation to children, particularly in light of recent changes to pediatric allocation policy (**Exhibit A**). Under new pediatric heart allocation policy, pediatric status 1B candidates are expected to rise in number, while fewer candidates will qualify for pediatric status 1A. Unfortunately, under the original proposed policy, while most of the impact on pediatric recipients resulted in earlier and therefore more beneficial allocation to pediatric candidates, allocation to pediatric status 1B candidates in Zone A would be negatively impacted, with allocation occurring to the following groups first: adult status 1 or 2 candidates in the donor's DSA, Zone A, or Zone B, and adult status 3 and 4 in the donor's DSA. While the allocation to adult status 1 or 2 is not expected to have a large impact due to the small number of candidates in those statuses, there is expected to be a large number of adult status 4 candidates, potentially significantly impacting allocation to 1B pediatric recipients in Zone A.

The Committee confirmed the significant potential negative impact on pediatric status 1B recipients, and determined it should revise the proposed pediatric donor allocation sequence to eliminate potentially negative impacts. Because the current allocation policy change is directed primarily at adult candidates, the new policy should leave pediatric donor heart allocation unchanged to the extent possible. The revised public comment proposal aims to eliminate the negative impact on allocation to pediatric 1B recipients and to leave the current balance of geographic sharing within pediatrics unchanged. The revised public comment proposal limits broader sharing to Zone A, which also mitigates some of the negative impact on pediatrics.

<u>Detailed Definitions for Status Criteria</u>

The TSAMs projected the outcomes of heart candidates based on the straw man groups. However, as the Committee developed the proposal, it became clear that the candidates that qualify for a status should be more specifically defined, by physiological parameters when possible, to ensure that the status comprises the patients that are truly urgent. Feedback received from the Forum on U.S. Heart Allocation

Policy in November 2013[6] and a forum hosted by the American Society of Transplantation (AST) in May 2015[7] emphasized that the definitions for the candidates that qualify for each status should be very clear.

The Committee sought additional clinical input for establishing the parameters for each of the status criteria during and after public comment. Committee members led and participated in discussions at various forums, including at the Cutting Edge of Transplantation conference hosted by AST in February 2016, the International Society of Heart & Lung Transplantation (ISHLT) annual conference in April 2016, and the American Transplant Congress (ATC) in June 2016.

Additionally, the Committee distributed a survey developed to elicit additional feedback on how to revise policy with regard to geographic sharing, and candidates supported by VA ECMO, acute circulatory support devices, and LVADs. The survey was distributed to heart transplant program administrators and program directors, OPO executive directors, and the following OPTN/UNOS Committees: OPO, Pediatric, Transplant Coordinator, Transplant Administrator, and Minority Affairs Committees. The link was also posted on the ISHLT blog. The survey was open from June 13 through June 24, 2016, and the Committee received 169 responses.

Consensus largely supports creating additional qualifying criteria for the most urgent statuses, and establishing a higher level of review for extending urgent statuses for candidates that are supported by therapies intended to be temporary. The Committee proposes imposing additional criteria for initially qualifying for status 1 under the VA ECMO criterion, status 2 under the percutaneous device and intra-aortic balloon pump criteria, and status 3 under the multiple inotropes with hemodynamic monitoring criterion. The proposal requires that these therapies are being used to treat cardiogenic shock.

Participants at the ISHLT annual conference suggested the Committee adopt the American Heart Association (AHA) definition of cardiogenic shock.[8] The Committee therefore proposes that, from a hemodynamic assessment within 7 days prior to administration of these therapies, the candidate's systolic blood pressure is less than 90 mmHg, pulmonary capillary wedge pressure is greater than 15, and cardiac index is either less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or less than 2.2 L/min/m^2 if the candidate is supported by inotropes. For those candidates whose hemodynamic measurements cannot be obtained within 7 days prior to support, then within 24 hours prior to support either the candidate's systolic blood pressure must be less than 70 mmHg, arterial lactate must be greater than 4 mmol/L, aspartate transaminase (AST) or alanine transaminase (ALT) must be greater than 1,000 U/L, or CPR must have been performed on the candidate.

The Committee debated how long the initial qualifying period should last for each of these criteria. The Committee considered shortening the initial period to 7 days, particularly for VA ECMO and percutaneous circulatory support devices, because the community generally agrees that these therapies should not be used for a period longer than 7 days. The results of the TSAM demonstrate that on average the 50-55 patients ever on ECMO included in the TSAM cohort were supported by ECMO for between 2 to 4 days.[9] However, data show that 15 percent of candidates were supported by these therapies longer than 7 days. Within the TSAM cohort, under the proposed sharing scheme ("6 urgency statues with broader sharing") described in the "**How well does this proposal address the problem statement?"** section below, the maximum number of days a candidate was supported by ECMO is 8. Additionally, the survey results supported permitting these candidates to be registered in their respective statuses for 14 days. For the second round of public comment, the Committee ultimately determined that the 14 day initial period is

[6] J.A. Kobashigawa, M. Johnson, J. Rogers, J.D. Vega, M. Colvin-Adams, L. Edwards, D. Meyer, M. Luu, N. Reinsmoen, A.I. Dipchand, D. Feldman, R. Kormos, D. Mancini and S. Webber on behalf of the forum participants. Meeting Report: Report from a Forum on US Heart Allocation Policy. American Journal of Transplantation 2015; 15: 55–63. doi: 10.1111/ajt.13033.
[7] J.A. Kobashigawa,, J. Teuteberg, M. Colvin, L. Edwards, T. Daun, M. Luu, J. Patel, J. D. Vega, and D. Meyer on behalf of the forum participants. Meeting Report:Proceedings of the AST Heart Allocation Meeting at the American Transplant Congress, Philadelphia, Pennsylvania, May 4, 2015. Clinical Transplantation 30, no. 5 (May 2016): 641-48. doi:10.1111/ctr.12717.
[8] Reynolds, H.R. and Hochman, J.S. Cardiogenic Shock: Current Concepts and Improving Outcomes. *Circulation*. February 5, 2008. Circulation AHA
[9] Skeans M and Audette K. Memorandum: Simulated time spent using selected heart status criteria. June 27, 2016.

appropriate, but decided to establish stringent criteria for extending a candidate's registration in these statuses beyond the initial 14 day period. However, in response to additional feedback received during the second round of public comment (**Exhibit B**), the Committee ultimately proposes limiting the initial status 1 qualifying period for candidates supported by VA ECMO to 7 days, as described in the **"Was this proposal changed in response to public comment?"** section below.

There is consensus that, after the initial period of 14 days (or 7 days for VA ECMO), the decision to continue supporting a candidate with a temporary therapy (VA ECMO, acute circulatory support devices, intra-aortic balloon pumps, and non-dischargeable left ventricular assist devices (LVADs)) often becomes a choice rather than a necessity. The community criticized the original public comment proposal for incentivizing practitioners to leave their candidates on temporary support for longer than clinically indicated solely to grant their candidates access to the higher statuses. Participants at the ISHLT annual conference and the survey responses also largely supported establishing a higher level of review for extending the high urgency statuses related to temporary support. Therefore, the Committee proposes requiring transplant programs to apply to the regional review boards (RRBs) to extend a candidate's registration after their initial period if they are supported by VA ECMO, an acute circulatory support device, a non-dischargeable LVAD, or an intra-aortic balloon pump. The transplant program must provide the RRB with evidence that the candidate has a contraindication to being transitioned to durable support, and objective evidence of a failure to wean the candidate off the current support. The proposal specifies precisely the evidence the transplant program must provide the RRB.

If the candidate remains supported by these therapies but the RRB either does not grant an extension or the transplant program does not request one, the Committee proposes these candidates qualify for status 3. The Committee believes status 3 is an appropriate status, because the candidates continue to have a wait list mortality risk comparable to others in the high urgency statuses, but in status 3 they will no longer have access to broader sharing. This ensures that the candidates are appropriately stratified based on risk while removing an incentive to continue what is generally believed to be more temporary therapy.

Changes to other qualifying criteria are detailed below. If a sub-criterion is not mentioned below, then the revised public comment proposal does not include significant changes to the original public comment proposal.

Status 1

- Status 1: Continuous Mechanical Ventilation

The Committee debated whether continuous mechanical ventilation should remain in policy. Committee members noted that continuous mechanical ventilation is not usually an indication for heart transplant, and, like ECMO, these candidates may have a higher post-transplant mortality. The Committee reviewed data regarding the number of transplant recipients that were registered as status 1A under the continuous mechanical ventilation criterion at the time of their transplant. Between 2012 and 2014, over 420 patients used continuous mechanical ventilation as status 1A criteria at least once, and about 20 patients per year received transplants while registered as status 1A with continuous mechanical ventilation as the justification.[10]

Though the Committee included continuous mechanical ventilation in the original public comment proposal, it removed continuous mechanical ventilation as a justification for status 1 in the revised public

[10] Based on OPTN data presented on October 22, 2015.

comment proposal. The Committee reiterated that continuous mechanical ventilation is not an indication for heart transplantation, and candidates currently registered using continuous mechanical ventilation are likely to have collinear therapies that will qualify the candidates for other statuses.

- Status 1: Non-Dischargeable VADs

The Committee proposes re-naming this status criterion to "Surgically Implanted, Non-Endovascular Biventricular Support Devices." The original public comment proposal permitted anyone supported by a device that was not approved for use outside of the hospital by the U.S. Food & Drug Administration (FDA) to qualify for status 1. This proposal limits this criterion only to *biventricular* support devices that are not approved for use outside the hospital, and is intended to apply to those candidates whose devices were placed after undergoing a thoracotomy or median sternotomy. The revised public comment proposal also creates a status criterion in status 2 for those candidates supported by LVADs that are not FDA-approved for use outside the hospital.

Status 2

- Status 2: Total Artificial Heart (TAH), Dischargeable Right Ventricular Assist Device (RVAD), BiVAD, or Single Ventricle Patients with LVAD

The revised public comment proposal combines the TAH criterion and RVAD, BiVAD, and single ventricle LVAD criteria into one, but otherwise does not change the rules for qualifying for this status.

- Status 2: Acute Circulatory Support (ACS) Device

The Committee proposes re-naming this criterion "Percutaneous Endovascular Mechanical Circulatory Support Device." The name change is intended to clarify exactly which devices would qualify a candidate to be registered under this criterion. The Committee also proposes including in the definition the term "without an oxygenator" to clarify that ECMO is not the type of support envisioned to qualify for this status. Like ECMO, the revised public comment proposal includes strict criteria to qualify using this justification for status 2, and also adopts the stricter extension criteria described above.

- Status 2: Intra-aortic Balloon Pump (IABP)

IABP is another therapy that is at risk for being used simply to qualify a candidate for a higher status. Therefore, like ECMO and percutaneous support devices, the revised public comment proposal includes strict criteria to qualify using this justification for status 2, and also adopts the stricter extension criteria described above.

Status 3

- Status 3: Dischargeable LVAD for 30 Days

Current policy permits stable candidates supported by a VAD to be registered as status 1A for 30 days at the transplant program's discretion. The Committee discussed whether the 30 day optional period should continue as a policy at all.[11] Those who oppose the discretionary 30 day time cite studies that show that stable LVAD patients are at a much lower risk of experiencing adverse events while waiting for transplant, and are therefore not nearly as urgent as other candidates in status 3.[12,13] Those who supported the optional 30 day period believe the TSAM analysis reveals that the candidates using the LVAD for 30 days discretionary time have lower waiting list mortality rates than others in status 3 as a direct result of an intentional compromise that provides candidates with a priority for a limited time without forcing them to risk developing a device complication in order to move up in urgency.

[11] D.M. Meyer; J.G. Rogers; L.B. Edwards; E.R. Callahan; S.A. Webber; M.R. Johnson; J.D. Vega; M.J. Zucker; J.C. Cleveland Jr., The Future Direction of the Adult Heart Allocation System in the United States. American Journal of Transplantation. 2015;15(1):44-54.

[12] Dardas T, Mokadam NA, Pagani F, Aaronson K, Levy WC. Transplant registrants with implanted left ventricular assist devices have insufficient risk to justify elective Organ Procurement and Transplantation Network status 1A time. J Am Coll Cardiol 2012; 60: 36–43.

[13] Pinney SP. Timing isn't everything: Donor heart allocation in the present LVAD era. J Am Coll Cardiol 2012; 60: 52–53.

During public comment, the Committee received mixed feedback regarding whether to perpetuate the 30 day optional period, and the Committee itself remained divided (**Exhibit A**). The Committee decided to include a question about whether to retain the 30 day discretionary period in the survey. Though the survey results were also nearly evenly split, more respondents (55%) were in favor of keeping the provision than not.

Ultimately, the Committee determined that the discretionary LVAD for 30 days policy should continue. It is an acceptable compromise that provides candidates supported by an LVAD with an opportunity for transplant while stable, which likely increases the opportunity for successful transplantation prior to the development of a device-related complication.

- Status 3: Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

This status was largely informed by the requirements in current policy. To avoid inadvertently creating an incentive to administer inotropes in order to register a candidate as status 3, the Committee adopted the similar cardiogenic shock requirements for the initial qualifying period as ECMO, percutaneous devices, and IABP. In addition to the extension criteria designed for ECMO, IABP and percutaneous devices, the Committee proposes an alternative means for extending a candidate in this status through proof the candidate failed an attempt to be weaned off of inotropic support. The Committee proposes permitting transplant programs to provide evidence to the RRB that the candidate cannot be weaned from their inotropes through an SvO_2 less than 50% measured by central venous catheter, because not all candidates supported by inotropes will have an invasive catheter.

Status 4

- Status 4: Inotropes without Hemodynamic Monitoring

The Committee proposed slight revisions to this criterion. The Committee was concerned that the cardiogenic shock requirements applicable to candidates that qualify for the multiple inotropes criterion in status 3 were too strict for those candidates in status 4 that are not necessarily admitted to the hospital. Therefore, to further distinguish candidates that qualify for the status 4 inotropes criterion from the status 3 inotropes criterion, the Committee proposes removing the blood pressure evidence from the cardiogenic shock requirement. Therefore, candidates that qualify for status 4 under this criterion would be treated with at least one inotrope for cardiogenic shock, as evidenced by a cardiac index of less than 2.2 L/min/m^2, and a pulmonary capillary wedge pressure of greater than 15 mmHg.

- Status 4: Congenital Heart Disease and Amyloidosis, Hypertrophic Cardiomyopathy (HCM), or Restrictive Cardiomyopathy (RCM)

During public comment, the Committee received feedback that the specific diagnostic criteria in status 4 were appropriate for some candidates, but that some candidates with these diagnoses face unique challenges (**Exhibit A**). Some suggested that the Committee create specific policy exceptions for these candidates to accommodate situations in which their conditions worsen quickly. The Committee determined that the variability in outcomes within these categories precludes strict definitions of appropriate exceptions in policy. Especially for patients with congenital heart disease, but also for others in this category, the current exception process remains the most appropriate way to attempt to stratify patients into appropriate statuses based on perceived risk of waitlist mortality. Additionally, the Committee believes that the exception process will be improved because RRBs will review cases from other regions, rather than their own, which may eliminate any perception of unfairness that exists with the current RRB case review process.

Status 5

- Status 5: Combined Organ Transplants

This status is reserved for heart transplant candidates that are registered on the waiting list at the same transplant hospital for another organ. If a heart candidate also requires another organ, and qualifies for a more urgent status, the candidate should be registered at that status instead. This criterion is intended to

capture those candidates that do not otherwise qualify for a more urgent heart status but are registered for a second organ.

During public comment some confusion arose about the intent of this criterion. This criterion and this proposed policy do not change multi-organ allocation policy, nor the way in which multi-organ allocation will occur. Multi-organ allocation is an issue that will be addressed by a broader community of OPTN members in the future.

Additional Policy Clarifications

- Policy for Sensitized Candidates

On multiple occasions, the Committee discussed how to identify and prioritize sensitized patients. Though the Committee discussed multiple solutions, including review board exceptions or prioritization for candidates with a Calculated Panel Reactive Antibody (CPRA) of 80 percent and with three positive prospective cross-matches, the problem remains that this is not currently a required data field for transplant programs to complete, so the OPTN does not collect sufficient data on heart patients to strongly support any of these solutions. The Committee therefore proposes collecting CPRA data for candidates at intervals described in the "**Will this proposal require members to submit additional data?**" section below.

In the meantime, the Committee previously proposed a minor clarification to *Policy 6.3.B: Exceptions to Allocation for Sensitized Patients*. Current policy permits an OPO to allocate a heart out of sequence within a DSA to a sensitized candidate if the OPO and all transplant programs within the DSA agree. The proposed policy also permits this, but adds a restriction that the heart may be allocated out of sequence within the DSA but only within a status. The Committee believes this restriction is necessary because with broader sharing, an out-of-sequence allocation within a DSA would have a larger impact on candidates in Zone A than it would in the current system.

Because this policy may have a larger impact on candidates outside the DSA, the Committee also considered other options for modifying this policy. One option was to further modify the current policy to permit a sensitized candidate within the DSA to be prioritized for offers, but only to the extent that the candidate would not receive offers ahead of a candidate in Zone A that would otherwise be registered before the candidate. This option recognizes that even though transplant programs and the OPO in the DSA may agree to prioritize a candidate, all transplant programs in Zone A would not have the opportunity to do so and it would not be fair to prioritize a local candidate ahead of the Zone A candidate. Another option was to delete the policy altogether, and to require transplant programs to request exceptions from the RRB if the candidate is highly sensitized. Ultimately, the Committee agreed to propose the sensitization policy as written during the second round of public comment.

- RRB Policy

The Committee proposes clarifications to *Policy 6.3.A: RRB and Committee Review of Status Exceptions*, to streamline the RRB appeals process. The impetus for this proposed change is that candidates registered in the highest urgency statuses are expected to receive offers more quickly under the proposed adult heart allocation policy changes, so the review process for exceptions to be registered in these high urgency statuses should be explicitly clear.

The Committee considered whether exception requests should be decided by RRBs prospectively instead of retrospectively. A prospective review would ensure that candidates are not transplanted at a status that is not approved upon peer review by the RRB. However, prospective reviews are less favorable to the candidate, as the candidate is not permitted to be listed in the requested status until the RRB approves the request, which may take days. Conversely, retrospective reviews permit the candidate to wait in the requested status immediately, but the transplant program runs a risk that the candidate's assignment to that status will not ultimately be approved by the RRB. Due to the logistical challenges of obtaining RRB

approval prospectively in a timely manner, the Committee ultimately decided to continue to permit exception requests to be reviewed retrospectively.

Retrospective reviews present the possibility that a candidate will be transplanted before the RRB can review the request, and, if the RRB does not ultimately approve the request, the candidate would have been transplanted while in a status that reviewers do not agree was warranted. To ensure that transplant programs do not try to take advantage of this possibility, the Committee proposes giving the Thoracic Committee clear authority to review cases in which a candidate is transplanted at an unapproved status, and to determine whether the transplant program at which the candidate was registered should be referred to the Membership and Professional Standards Committee (MPSC) for further review. It is not a policy violation in and of itself to transplant a candidate before the exception request is granted, but the new policy does require transplant programs to pursue the request even if the candidate is transplanted to ensure that ultimately, the RRB or the Thoracic Committee approves of the candidate's registration in the requested status. Therefore, if a candidate is transplanted before the final disposition of the exception request, and the transplant program does not pursue the exception process to the point where the exception is approved by either the RRB or the Thoracic Committee, the case could be referred to the MPSC.

- Heart-Lung Allocation Policy

The Committee proposes additional policy clarifications that are necessary due to the change in status criteria and definitions. First, the Committee proposes changes to *Policy 6.5.F: Allocation of Heart Lungs*, to clarify that when allocating a heart-lung block from the lung or heart-lung match run, the OPO does not need to first offer the heart to all eligible heart-alone candidates in all zones. Instead, if the OPO generates a lung or heart-lung match, the OPO can offer the heart-lung to heart-lung candidates after offering the heart to all eligible adult status 1, 2 and 3 candidates and pediatric status 1A and 1B candidates within the DSA or Zone A (as described in the **"Was this proposal changed in response to public comment?"** section below). The Committee proposes equating proposed adult status 1, 2 and 3 candidates to current status 1A candidates for the purposes of this section of policy. This clarification closely mirrors the guidance the Committee previously developed.[14]

How well does this proposal address the problem statement?

The Committee requested two TSAM analyses as it developed this proposal in order to simulate the impact of the proposed changes. The first simulation analysis demonstrated the projected impact of stratifying candidates based on a 6-tiered urgency system, rather than the current three tiers. The allocation rules for the first analysis were otherwise intended to mimic current allocation policy as closely as possible, so the first analysis does not include allocation which shares donated organs more broadly than the current allocation system. The second analysis was based on the proposed 6 urgency statuses, but also incorporated broader sharing schemes into the allocation rules.

For each analysis, the SRTR performed ten runs of the TSAM using a cohort of candidates and donors drawn from real data between 2009 and 2011. Each simulation run uses the same list of historically-derived donors and candidates from the cohort, but changes the order in which the donors appear, thus changing the order of candidates to whom offers are made. The simulations are run ten times with these different orderings to account for a range of variability. Thus, simulation results show a range of outcomes across the ten runs, as well as a point estimate of the average across the ten runs (ranges do not indicate confidence limits). The first TSAM analysis, which tested the projected impact of the 6-tiered urgency system with the current geographic sharing rules, showed reductions in overall waiting list mortality rates, increases in transplant rates among the most urgent patients, and similar post-transplant mortality overall

[14] "Guidance to Organ Procurement Organizations for Allocation of Heart-Lung Blocks." OPTN Heart Lung Allocation Guidance (last visited January 15, 2016)

as compared to the current system.[15] Results of the first analysis are included in the figures in this proposal as "6 StatGrps" and will be referenced throughout this section as "6 urgency statuses."

The second TSAM analysis used the same cohort and builds on the results of the first analysis of the 6 urgency statuses. The Committee requested the SRTR model four different broader sharing schemes, and the results are included in the second analysis report.[16] The Committee ultimately decided to design the proposal based on the results shown for the modeling scheme shown in **Figure 5** below (Column: Location in Original Public Comment Proposal). The original proposed scheme is demonstrated in the following figures as "6 GrpShare" and will be referenced throughout this section as "6 urgency statuses with broader sharing."[17]

Figure 5: 6 Urgency Statuses Plus Broader Sharing; Original Public Comment Proposal vs. Revised Public Comment Proposal

New candidate status	Location in Original Proposal (6 GrpShare)	New candidate status	Location in Revised Proposal (6 StatGrps)
Status 1 adult + Status 1A pediatric	DSA + Zone A	Status 1 adult + Status 1A pediatric	DSA + Zone A
Status 1 adult + Status 1A pediatric	Zone B	Status 2 adult	DSA + Zone A
Status 2 adult	DSA + Zone A	Status 3 adult + Status 1B pediatric	DSA
Status 2 adult	Zone B	Status 1 adult + Status 1A pediatric	Zone B
Status 3 adult + Status 1B pediatric	DSA	Status 2 adult	Zone B
Status 4 adult	DSA	Status 4 adult	DSA
Status 3 adult + Status 1B pediatric	Zone A	Status 3 adult + Status 1B pediatric	Zone A
Status 3 adult + Status 1B pediatric	Zone B	Status 3 adult + Status 1B pediatric	Zone B
Status 5 adult + Status 2 pediatric	DSA	Status 5 adult + Status 2 pediatric	DSA
Status 6 adult + Status 2 pediatric	DSA	Status 6 adult + Status 2 pediatric	DSA
Status 1 adult + Status 1A pediatric	Zone C	Status 1 adult + Status 1A pediatric	Zone C
Status 2 adult	Zone C	Status 2 adult	Zone C
Status 3 adult + Status 1B pediatric	Zone C	Status 3 adult + Status 1B pediatric	Zone C
Status 4 adult	Zone A	Status 4 adult	Zone A
Status 5 adult	Zone A	Status 5 adult	Zone A
Status 6 adult + Status 2 pediatric	Zone A	Status 6 adult + Status 2 pediatric	Zone A
Status 1 adult + Status 1A pediatric	Zone D	Status 1 adult + Status 1A pediatric	Zone D
Status 2 adult	Zone D	Status 2 adult	Zone D

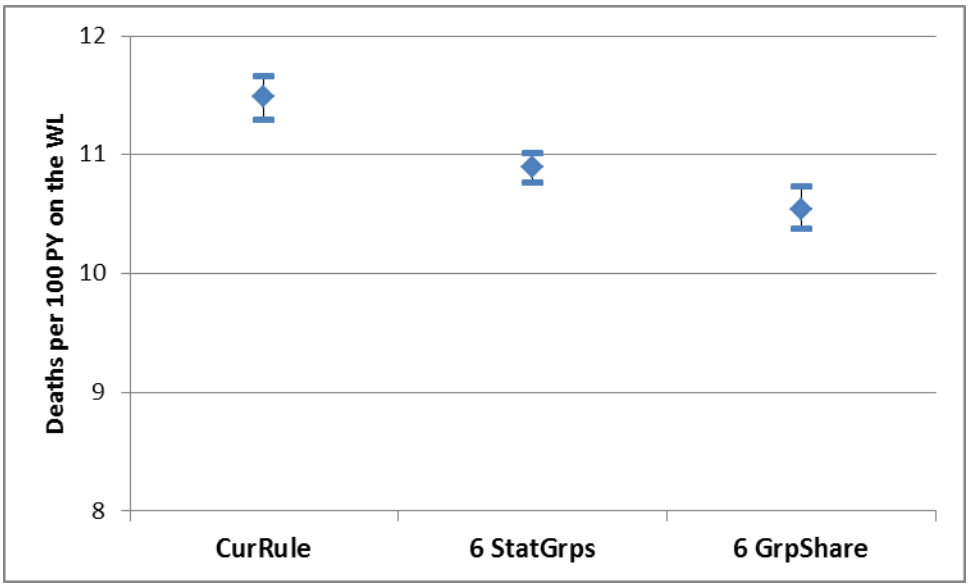
[15] Colvin M, Pyke J, Skeans M, Wang X, Zeglin J. Final Analysis: Data Request from the Heart Subcommittee of the Thoracic Organ Transplantation Committee. Data Request ID: HR2014_05. March 23, 2015.
[16] Colvin M, Bolch C, Pyke J, Skeans M, Wang X, Zeglin J. Analysis Report: Data Request from the Heart Subcommittee of the OPTN Thoracic Organ Transplantation Committee. Data Request ID: HR2015_01. October 26, 2015.
[17] The data displayed in these figures as under the heading of "6 GrpShare" corresponds with the "Sh 1/2A" data in the second TSAM report.

New candidate status	Location in Original Proposal (6 GrpShare)	New candidate status	Location in Revised Proposal (6 StatGrps)
Status 3 adult + Status 1B pediatric	Zone D	Status 3 adult + Status 1B pediatric	Zone D
Status 4 adult	Zone B	Status 4 adult	Zone B
Status 5 adult	Zone B	Status 5 adult	Zone B
Status 6 adult + Status 2 pediatric	Zone B	Status 6 adult + Status 2 pediatric	Zone B
Status 1 adult + Status 1A pediatric	Zone E	Status 1 adult + Status 1A pediatric	Zone E
Status 2 adult	Zone E	Status 2 adult	Zone E
Status 3 adult + Status 1B pediatric	Zone E	Status 3 adult + Status 1B pediatric	Zone E
Status 4 adult	Zone C	Status 4 adult	Zone C
Status 5 adult	Zone C	Status 5 adult	Zone C
Status 6 adult + Status 2 pediatric	Zone C	Status 6 adult + Status 2 pediatric	Zone C
Status 4 adult	Zone D	Status 4 adult	Zone D
Status 5 adult	Zone D	Status 5 adult	Zone D
Status 6 adult + Status 2 pediatric	Zone D	Status 6 adult + Status 2 pediatric	Zone D
Status 4 adult	Zone E	Status 4 adult	Zone E
Status 5 adult	Zone E	Status 5 adult	Zone E
Status 6 adult + Status 2 pediatric	Zone E	Status 6 adult + Status 2 pediatric	Zone E

As described in the "**How was this proposal developed?**" section above, the Committee now proposes a revised version of six urgency statuses with broader sharing. The primary change is the limitation of the initial broader geographic sharing to status 1 and 2 candidates within the donor's DSA or Zone A. Status 1 and 2 candidates in Zone B are now classified after status 3 patients within the donor's DSA (**Figure 5**: Column: Location in Revised Public Comment Proposal).

The second TSAM analysis examining the use of the six urgency statuses with broader sharing rules indicated that waiting list mortality rates appeared to decrease under the broader sharing rules as compared to current rules or rules incorporating new statuses but without broader sharing (**Figure 6**). The overall waiting list mortality rates in the proposed system are likely to decrease because organs will be allocated to sicker patients more quickly, removing these candidates from the pool of those at risk for dying while waiting. Candidates that are less urgent might not be transplanted as quickly, but they are also less likely to die while waiting.

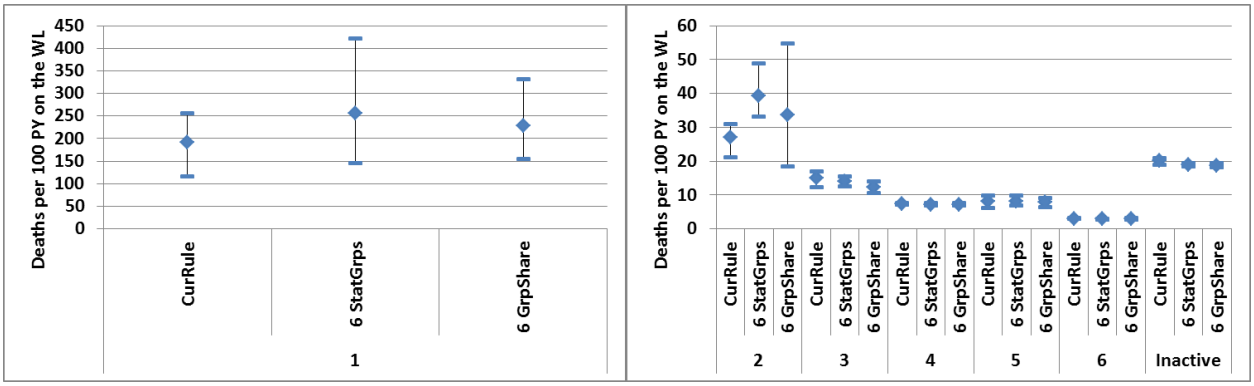
Figure 6: Overall Waitlist Mortality Rates by Simulation



Waiting list mortality rates under the six urgency statuses and 6 urgency statuses with broader sharing appear to increase for patients at the highest urgency statuses compared to current rules (status 1 or 2, **Figure 7**). However, this change predominantly reflects the shorter waiting time for candidates at these statuses under the modeled changes, rather than an increase in the incidence of mortality. Specifically, the actual occurrence of death in the model ranges between 4 and 9 status 1 candidates with broader sharing, compared to 11 to 19 deaths under current rules and 7 to 18 deaths with six urgency statuses without broader sharing. Thus, while the rate estimate is higher in the proposed system, the number of status 1 and 2 candidates predicted to die while waiting is lower than the current system. The rate increases because patients are either dying or being transplanted rapidly at these urgencies, so the time on the waiting list (the denominator) is decreasing.

The waiting list mortality rates for candidates registered as inactive also decrease in the proposed system, because more urgent candidates are projected to be transplanted before reaching a state in which they are too ill for transplant and transferring to “inactive” status (**Figure 7**). This reduces the number of waiting list deaths and decreases overall waiting list mortality rates.

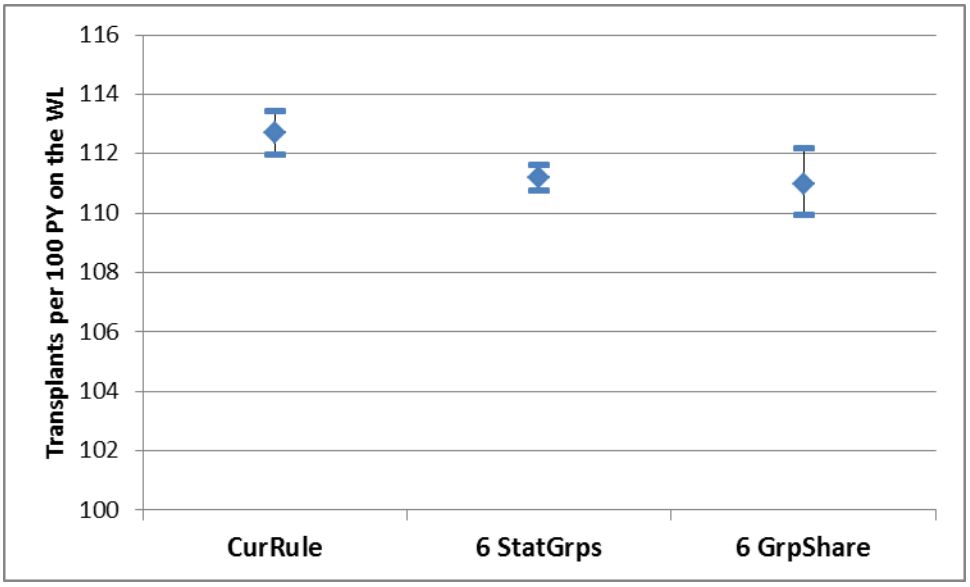
Figure 7: Waitlist Mortality Rates by Simulation and New Status Groups, Adult Candidates



To combat the high waiting list mortality for the most urgent patients, the Committee determined that it should allow these candidates access to a broader geographic range of donors. Because of this, the waiting list mortality rates for statuses 1, 2, and 3 noticeably decrease in the six urgency statuses with broader sharing scheme compared to the 6 urgency statuses. Though status 1 candidates exhibit the highest projected waiting list mortality rates, the rates are comparable to the rates in the current system, and the absolute number of deaths while waiting is notably lower. Additionally, the waiting list mortality rate for status 3 declines in the six urgency statuses with broader sharing scheme, which affects a much larger group of patients than those that would qualify for proposed statuses 1 and 2.

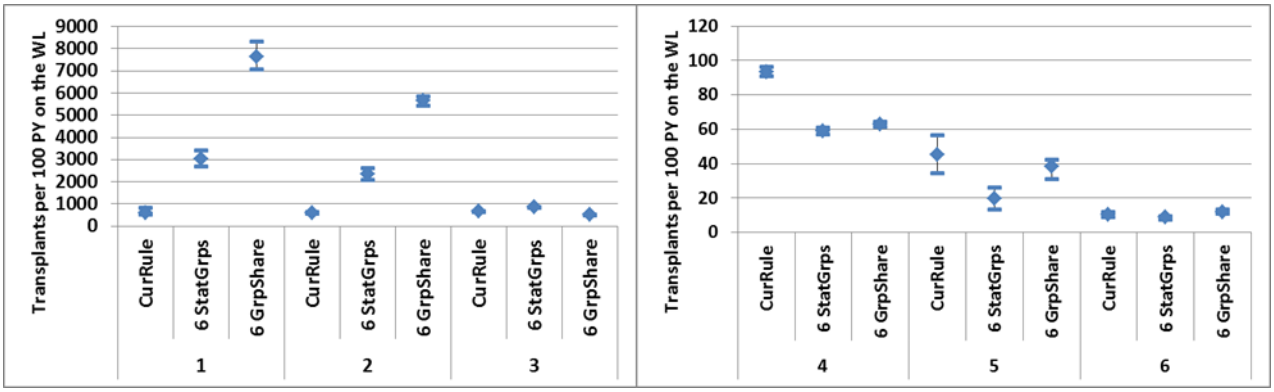
Overall transplant rates by simulation appeared to be slightly lower in the proposed sharing schemes than in the current rules. See **Figure 8**. However, the ranges of some sharing rules overlapped with the ranges exhibited in the current rules simulation. It is also important to remember that the bars in this graph represent the minimum and maximum results of the ten simulated runs; they are not the 95% confidence limits.

Figure 8: Overall Transplant Rates by Simulation



Importantly, the proposed system is intended to ensure that the most urgent candidates are transplanted more quickly, and the TSAM analysis of the proposed geographic sharing schemes demonstrate this goal (**Figure 9**). Note that the upper y-axis limit is 9000 on the left panel and 120 on the right panel.

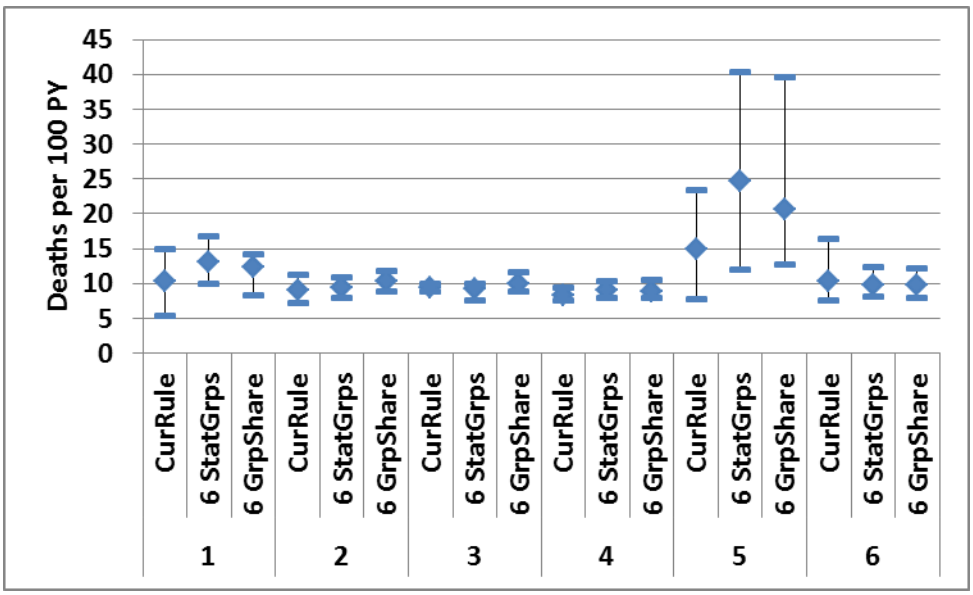
Figure 9: Transplant Rates by Simulation and New Status Groups, Adult Candidates



The Committee designed the proposed system to ensure that candidates most in need of transplant are prioritized in allocation. Broader sharing is projected to increase the transplant rates in status 1 and 2 because there are increased transplant counts and decreased waiting times for these patients, which contribute to higher rates. Under the current rules simulation, there are 51 transplants in status 1, but when applying broader sharing, the transplant counts increase nearly four-fold to 191. Status 1 transplant rates increase even more, from 615 transplants per 100 years on the waitlist under current rules, to 3,044 with six statuses, to 7,627 with six statuses plus broader sharing. The same pattern occurs in status 2. Increased transplant rates for these statuses under broader sharing are expected; the more priority given to statuses 1 and 2, the more one would expect to see the patients in these statuses receiving transplants. Transplant rates for status 3 candidates appear similar when comparing the current sharing rules to the proposed 6 urgency statuses with broader sharing. Status 4 candidates exhibit lower transplant rates for the two simulations involving the proposed statuses compared to the simulation based on current rules, but this was also expected. Importantly, there is not a marked increase in death counts, meaning the candidates wait longer, but are not dying more frequently.

In the proposed system, within each status the post-transplant mortality rates are projected to remain comparable to those rates in the current system (**Figure 10**). One-year post-transplant mortality rates show a similar pattern.

Figure 10: Two-Year Post-Transplant Mortality Rates by Simulation and Tier, Adult Recipients



The post-transplant mortality rates for the simulations based on broader sharing trend slightly higher than the simulation based on current rules. The Committee expressed concern about unintentionally increasing post-transplant mortality rates as a result of increasing transplants in the most urgent patients. While status 1 post-transplant mortality rates appear to increase slightly, the modeling may not as accurately predict whether those candidates would do better if they were transplanted more quickly, as the post-transplant mortality models are based on outcomes in recipients transplanted under current rules, where all status 1A candidates receive the same priority. It is possible that these candidates may begin to have improved post-transplant mortality due to shorter wait times at the highest urgency. These are candidates that may have otherwise died while waiting for transplant.

The post-transplant death rates in status 1 are higher than in status 2, but are also based on a smaller death count. This result is expected because the number of transplants for status 1 candidates is likely to increase, and the modeling appears to show the post-transplant death rate rising in concert with the increased rate of transplants for candidates in the same status. The Committee agreed that though status 1 candidates may experience slightly higher post-transplant mortality rates, prioritizing them is a clinically acceptable compromise, particularly when delaying transplantation would likely result in death on the waiting list.

Based on the analyses described above, the Committee anticipates the proposed policies will decrease waiting list mortality rates by increasing transplant rates for the most urgent candidates by ensuring they are properly escalated to the most urgent status, and have access to the broadest range of donors. Such changes are not anticipated to negatively impact waiting list mortality rates for candidates in less urgent statuses. Additionally, while post-transplant mortality rates may increase slightly for the most urgent candidates, the Committee believes this is an appropriate risk in order to benefit the candidates most in need.

Was this proposal changed in response to public comment?

This proposal represents over four years of work, two rounds of public comment and deliberate outreach efforts to the heart transplant community and patient advocacy groups, whose feedback has helped shaped this iteration of the proposal. Many of the compromises the Committee made in response to the first round of public comment are detailed in **"How was this proposal developed?"**

In the second round of public comment, six of the eleven regions supported the proposal in its entirety, and just two disapproved of it (**Exhibit B**). The three remaining regions opposed certain aspects of the statuses but supported broader sharing. Several OPTN/UNOS committees reviewed the proposal: Minority Affairs, MPSC, Transplant Coordinators, OPO, Pediatric and Patient Affairs. All were either supportive or neutral of the changes made. The proposal also garnered feedback from several individual transplant programs and the following societies; their input is noted in subsequent sections below:

- International Society of Heart and Lung Transplantation (ISHLT)
- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- Society for Thoracic Surgeons (STS)
- American College of Cardiology (ACC)
- Association of Organ Procurement Associations (AOPO)
- North American Transplant Coordinators Organization (NATCO)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- Hypertrophic Cardiomyopathy Association (HCMA)

Although the proposal received fewer responses this round of public comment, several similar themes identified in the first round of public comment emerged. In addition, the Committee received substantive feedback to the questions for which the Committee specifically requested feedback. The themes, and the Committee's response, are detailed below.

Broader Sharing

Limiting sharing to only Zone A appeased some in the community; several comments supported broader sharing generally or the compromise to limit broader sharing though Zone A for just the highest statuses. Three regions that did not support the statuses supported this aspect of the proposal.

Those who opposed even the more limited sharing cited similar concerns voiced in the first round of public comment: increased travel time and costs due to more "flyouts" and organ transport generally; increased cold ischemic time that could result in increased discards and negative outcomes; increased allocation time; and compromised local relationships between the OPO and transplant programs.

One region suggested offering a heart to all candidates in statues 1-6 in the DSA and Zone A before offering it to Zone B (and beyond). It feared a majority of its patients in statuses 3-6 would never receive offers under the proposed sharing scheme. It also asserted the proposed scheme does not address "equity:" patients would be forced to relocate to regions with more favorable waiting times, which would disenfranchise those without the economic ability to afford such a move.

The Committee considered public comment feedback but ultimately decided to keep the proposed Zone A sharing scheme. The proposal is primarily aligned with the UNOS/OPTN strategic goal of providing equity in access to transplants, which seeks to reduce geographic disparity in access to transplantation. In addition, this proposal aims, in part, to align heart allocation with the Final Rule. The Final Rule states that OPTN/UNOS allocation policies must, among other factors, seek to achieve the best use of donated organs and shall not be based on the candidate's residence or place of listing. The Committee believes the proposed scheme strikes the proper balance between sharing across a wider geographic area without increasing cold ischemic time or risking transplanting organs or unnecessarily increasing the need for organ procurement-related travel expenses and time.

Statuses

- Status 1: VA ECMO

Overwhelmingly, a majority of the status 1 feedback pertained to VA ECMO. Three sub-themes emerged: the initial qualifying period VA ECMO in status 1 should be limited to 7 days; VA ECMO should not be prioritized as high as status 1; and VA ECMO should not be included in the criteria at all, because those candidates should not be transplanted due to poor outcomes. Several commenters also suggested capping the qualifying time for status 1 at 14 days and not allowing these candidates an extension.

As this was perhaps one of the more controversial components of the proposal, the Committee debated several options. First, it considered removing VA ECMO from policy altogether and instead requiring transplant programs to request an exception each time. However, this would contradict two of the proposal's goals: reduce waiting list mortality rates, of which VA ECMO candidates exhibited the highest; and reduce the use of exceptions to qualify for a status by better accommodating all candidate groups within the heart allocation system. Likewise, the next option the Committee considered, moving VA ECMO to a lower status, is not in line with the premise to stratify candidates by waitlist mortality. The Committee then considered keeping ECMO in status 1 for 14 days without the ability to extend, or keeping VA ECMO in status 1 but scaling back from 14 days to 7 days. Eliminating the ability to extend would disadvantage patients without options other than ECMO. Therefore, the Committee opted to scale VA ECMO back to 7 days, as this solution had the broadest community support. The decision to extend the criteria to 14 days following the first round of public comment was based on a majority (~80 percent) of survey respondents supporting that timeframe. However, during the discussions at the ISHLT annual meeting in April 2016, most attendees were in favor of keeping VA ECMO in status 1 if the qualifying period was limited to 7 days. In addition, throughout both public comment periods and at regional meetings, there was concern about encouraging the prolonged use of VA ECMO to the detriment of waitlist and post-transplant outcomes. Therefore, the Committee was amenable to changing the initial status timeframe and extension period from 14 days for these candidates to 7 days.

In addition, there was a recommendation to include a timeframe around the failure to wean criteria to be clearer about *when* the transplant program attempted weaning before requesting an extension. The Committee acknowledged that including a timeframe around the failure to wean criteria was reasonable, and added a 48 hour time period within which a transplant program failed to wean a candidate from specific therapies prior to an extension request. The Committee proposes including this change throughout the proposal in every policy in which failure to wean is a prerequisite for the Review Board to grant an extension.

- Status 2:

  Public comment regarding status 2 pertained to IABP use and the stratification of device-related infection or complications and malfunction (**Exhibit B**). Several commenters asserted that IABP is not comparable in urgency to other conditions in status 2, as these devices are easier to insert and allows patients to be ambulatory. In addition, some commenters believe the use of IABP would increase because transplant programs would be incentivized to use IABP to help their candidates qualify for a higher status. There was also concern over the status assignments for instances of device-related infection and malfunction. These criteria are both currently awarded 1A status and in the newly proposed stratifications, these criteria are stratified among statuses 2 and 3. Several commenters felt the division of these criteria was unjustified, as their urgency was comparable. With regard to both IABP and MCSD device-related complications, the Committee felt that reliance on actual waitlist mortality rates (rather than anecdotal reports or individual experiences with these devices) as appropriate criteria for status assignment. The Committee reviewed showed a clear demarcation in waitlist mortality between candidates with various device complications and infections and patients supported with an IABP had waitlist mortality equivalent

to other patients stratified into Status 2. Based on this data, the Committee felt that it would not be appropriate to change the status assignment of either of these groups of patients.

In addition, some members in Region 5 opposed the phrase "the candidate demonstrated a contraindication to being supported by a durable device" in the extension criteria in *Policy 6.1.B.i Non-Dischargeable, Surgically-Implanted, Non-Endovascular Left Ventricular Assist Device.* These members believe this language dictates clinical practice in encouraging use of durable devices when a surgically implanted non-durable device is clinically sufficient to manage the patient. Region 5 also stated that requiring programs to prove contraindications is not an appropriate function of the OPTN. The Committee responded that the community at large, through public comment and other fora, recommended including this language in an attempt to prevent programs from keeping candidates on a temporary device longer than necessary to gain a higher status or access broader sharing. In addition, the Committee reasoned that this comment had not come up at any other regional meeting, or by any other individual, society or program. Thus, the Committee opposed removing this requirement.

- Status 3:

  Those who commented on status 3 reiterated the same concerns about stratification of device-related infection or complications and malfunction. Specifically, several commenters voiced concern that device complications represent immediate life threatening events and these candidates' life expectancy is at least as limited as many of the categories within status 2. The Committee considered these comments in conjunction with similar feedback regarding status 2 device malfunction and elected not to make a change based on the data supporting the proposal.

- Status 4:

  Status 4 feedback revealed concerns that CHD, HCM and amyloidosis candidates will be disadvantaged under this proposal. Several commenters, including the HCMA, indicated there are no mechanical support options for these patients and they do not require inotropes, so these patients are unlikely to qualify for a higher status. Current policy does not provide for any status upgrade based entirely on the etiology of a candidate's heart failure, so the Committee feels that assigning these patients to Status 4 represents an important acknowledgement of the higher mortality faced by these patients. However, despite a thorough review of exception requests among patients with CHD, HCM and RCM, it was not possible based on existing data to define a subset of patients with consistently higher mortality. Rather, the waitlist mortality of these patients placed them clearly within Status 4. However, the Committee recognizes that some patients with these diagnoses will have higher mortality and may not be candidates for the mechanical support options leading to higher status within the policy. In the short-term the exception and review process will have to accommodate these patients (who can still be listed at as high a status as their predicted mortality would warrant, including Status 1). In the longer-term, the Committee expects that improved data collection will enable better stratification of these candidates to better accommodate them within the policy. The HCMA pointed out that leaving regional review boards to determine status assignments for these candidates based on exception requests would lead to inequitable variability for candidates with HCM. Ultimately, the Committee did not make changes to status 4 criteria, but agrees that guidance for status 4 diagnoses would be helpful to review boards in an attempt to standardize decision-making on exception requests. Additionally, the Committee believes that the change in review board practice, in which review boards will review cases from outside their own region, will minimize potential for biased decision-making.

Cardiogenic Shock Indicators

The Committee solicited specific feedback from the community on whether the cardiogenic shock indicators, added after the first round of public comment in response to feedback from the community, were appropriate. The Committee adopted the criteria from the American Heart Association (AHA) definition of cardiogenic shock. Some commenters agreed with the definition, others felt the criteria was too liberal, unspecific and variable from institution to institution.

The STS supported including hemodynamic assessment as criteria for qualifying candidates supported by VA ECMO, percutaneous circulatory support devices, IABP, and multiple inotropes, but asserted that hemodynamic assessment alone does not define cardiogenic shock. The STS stated that additional criteria should be added to the hemodynamic assessment to reflect and document the clinical presence of tissue malperfusion.

The Committee discussed this feedback. It continued to agree that the AHA definition was an appropriate definition to incorporate. However, the Committee decided to add a 24-hour timeframe within which the physiologic indicators for cardiogenic shock must be met. Otherwise, the Committee did not make any changes to the cardiogenic shock definition.

Policy for Sensitized Candidates

The Committee solicited specific feedback from the community on whether current policy for sensitized candidates (permitting the transplant programs and OPO in the donation service area to agree to allocate a donor heart to a sensitized candidate even if the candidate is not first on the match run) remain in place in light of the proposed broader sharing scheme. Several commenters agreed that the current policy should remain in place, while others voiced concern that this policy had not been revised and that sensitized patients were at a disadvantage. The latter group offered additional potential solutions:

- Include sensitized candidates in Status 3
- Remove current policy, require centers to request exceptions and develop guidance for RRBs
- Work with the Histocompatibility Committee to develop prioritization criteria to increase sensitized patients' chance of getting HLA compatible donors
- Replicate policies from other allocation systems:
    - Canadian system[18] - high CPRA patients (greater than 80 percent) are placed in *Status 4S*
    - Kidney Allocation System (KAS)[19] – uses a point system to prioritize candidates based on their CPRA score
- Keep current policy, but restrict allocation exceptions for sensitized patients to those in Status 3-6
- Keep the current policy but add a provision that candidates would not be prioritized for an offer before candidates in Zone A

Faced with a lack of data to support a more substantive solution, the Committee determined to move forward with modifying the current policy to permit a sensitized candidate within the DSA to be prioritized for offers, but only to the extent that the candidate would not receive offers ahead of a candidate in Zone A that would otherwise be registered before the candidate. This option recognizes that even though transplant programs and the OPO in the DSA may agree to prioritize a candidate, all transplant programs in Zone A would not have the opportunity to do so and it would not be fair to prioritize a local candidate ahead of the Zone A candidate. While it may not yet be possible to incorporate prioritization or broader sharing for sensitized patients in the current proposal, data from these combined efforts will guide further policy changes that incorporate sensitization in the U.S. heart allocation system.

[18] Canadian Cardiac Transplantation Network Cardiac Transplantation Eligibility and Listing Criteria. 2012. http://www.ccs.ca/images/Affiliates/CCTN/FINAL_Cardiac_Transplant_Eligibility_and_Listing_Criteria_20121.pdf

[19] Policy 8.3 Kidney Allocation Points. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08

RRB Operations

A majority of commenters supported the Committee's proposal to have regional review boards review cases from other regions instead of their own, including STS and AST. Two regions, along with NATCO and the HCMA, opposed this concept. NATCO indicated that introducing outside reviewers from another region to an already complex process could potentially impose a level of disadvantage to the list of recipients within a particular region. The HCMA did not feel that having regional review boards review cases from other regions would address the variability in listing or review board decisions pertaining to their patient population, and they continue to advocate for a national review system for CHD, HCM and amyloidosis cases.

The Committee acknowledged these comments but ultimately decided to adopt this operational modification. The OPTN/UNOS Heart Regional Review Board Guidelines have been revised to include this change, but the updated guidelines won't go into effect until the new allocation policy is implemented. In the future, the Committee will explore whether to establish a national review board, including one with a pediatric component.

Data Collection

Public comment regarding data collection was largely favorable (**Exhibit B**). Many commenters expressed optimism that the data collected, despite the addition of a substantial number of data elements, will eventually lead to a heart allocation score system. The Committee requested specific feedback regarding which data elements are likely to be incorporated into a heart allocation score due to their potential to predict waiting list mortality or post-transplant survival, whether there were additional data elements the Committee had not proposed, and whether there were extraneous data elements on the list. In addition, the Committee wanted to know if there were any data elements that should only be collected on VAD patients. The societies' feedback was most helpful in answering these questions:

Society	Feedback
AST	*Missing data elements:* • MCS support: type of MCS support (TAH, Biventricular support, LVAD) • MCS complications (severe, moderate, mild) *Extraneous data element:* • Six-minute walk test *Data elements on VAD patients*: • MCS support: type of MCS support (TAH, Biventricular support, LVAD) • MCS complications (severe, moderate, mild)
ISHLT	*Data elements on VAD patients:* • LDH levels • Plasma free hemoglobin levels • Hemoglobinuria • TIA • Stroke or peripheral thromboembolic events • Transfusion requirement during an episode of gastrointestinal bleeding
STS	*Missing data elements:* • Heart rate at the time of hemodynamic assessment • Indices to assess right heart function such as right ventricular stroke work index and pulmonary artery index • Number of ICD discharges within the previous 6 months • Percent lymphocyte count

Society	Feedback
	• Serum uric acid level • Presence of congenital anatomy and type • Assessments of frailty • Assessments of nutrition; e.g., serum prealbumin • Assessments of pulmonary function *Extraneous data elements:* • Six-minute walk test distance and peak exercise oxygen consumption study are likely to have limited relevance for a candidate on acute forms of temporary circulatory support or ECMO
Other	*Missing data elements:* • Genetic data • Data elements specific to the CHD population, such as single ventricle anatomy

Based on public comment feedback, the Committee removed the six-minute walk test from the list of proposed data elements, and adopted all of the data elements for VAD patients recommended by ISHLT (**Exhibit B**). They considered the recommendations made by AST, STS and individual commenters, but felt they had captured the most critical data elements and wanted to mitigate the increased burden on transplant centers. These changes are reflected in the list of data elements in **Exhibit C**.

Additionally, the Committee clarified the requirements for how often transplant programs must report these data to the OPTN. The data must be reported with the submission of every status justification form. Justification forms for statuses 1 through 3 are valid for up to 14 days (with the exception of VA ECMO in status 1 which is valid for up to 7 days and LVAD in status 3 which is valid for up to 30 days), justification forms for status 4 are valid for up to 90 days, and justification forms for statuses 5 and 6 are valid for up to 180 days.

The Committee also included policy language to clarify that transplant programs are not required to perform additional tests in order to submit these data with each status justification form. However, if a transplant program has performed a test or if the data have been updated since the previous status justification form submission, the transplant program must report the most up-to-date data to the OPTN the next time it submits a status justification form.

Heart-Lung Allocation Policy

The Committee received a single comment regarding heart-lung policy. The proposal requires the heart to be allocated to adult status 1 and adult status 2 candidates and pediatric status 1A before allocating to heart-lung candidates. Region 4 suggested to limit allocating a heart to adult status 1 candidates only, rather than offering to both adult status 1 and adult status 2, particularly for heart-lung candidates with a high LAS score. These candidates may have a higher waitlist mortality than status 2 candidates. The region also felt **Table 6-10** needed to be clarified; the proposed language states, “The heart from the same deceased donor must only be offered to the heart-lung potential transplant recipient (PTR) after the heart has been offered to all…” pediatric status 1A, adult status 1 or status 2 isolated heart PTRs through the geographic zones. The language doesn’t state that the heart then has to be offered to heart-lung PTRs, only that it can’t be offered until adult status 1 and adult status 2 go first. The region felt it left open the option for the OPO to offer the heart to isolated heart statuses 3-6 and not offer to heart-lung candidates.

The Committee considered these comments and agreed the language is ambiguous in **Table 6-10**. In addition, the Committee felt if the intent of the proposed changes to heart-lung policy was to mirror current policy to the extent possible, then isolated hearts should also be offered to adult status 3 and pediatric status 1B candidates in each geographic zone before heart-lung candidates. Current adult

status 1A candidates are stratified between adult statuses 1-3, so it felt these candidates should not be excluded. As pediatric status 1B is equated with adult status 3, the Committee elected to include them as well.

Thus, the Committee made several changes to the language in **Table 6-10**, "The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all: Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs."

Impact to Pediatric Candidates

Although few in number, public comment in response to the changes proposed to mitigate impact to pediatric 1B candidates was favorable (**Exhibit B**). One of the overarching principles in developing the adult heart allocation scheme was that the Committee did not want to negatively impact pediatric candidates, so when possible, the proposal should be neutral or should benefit them. The OPTN/UNOS Pediatric Committee, ISHLT, and the Children's Hospital of Pittsburgh endorsed these changes.

Heart Allocation Score

The Committee received general feedback during both rounds of public comment that the proposal still over-emphasized waitlist mortality and under-emphasized post-transplant outcomes. Developing a HAS to balance both emerged as a theme again during the second round of public comment (**Exhibit B**). The ASTS pointed out that similar concerns regarding lack of data were expressed related to the lung allocation score (LAS) yet the Committee moved forward. The ACC was steadfast in its sentiment that a HAS is still the best solution to improve equitable distribution of organs to those in the greatest need on the waiting list. It asserted that a HAS would better determine need for transplant by identifying the sickest patients on the list who are anticipated to have good outcomes after heart transplant and avoids the potential use of therapies that may not be indicated and/or approved for certain patient populations. The Committee acknowledged these concerns in both rounds of public comment and concurs with the community that a HAS will ultimately be a great solution, but in the interim, it is imperative that the OPTN begin to collect relevant data that will inform a HAS in the future.

Which populations are impacted by this proposal?

All heart and heart-lung candidates will be impacted by this proposal. As of July 2, 2016, there are 4,088 heart candidates and 46 heart-lung candidates awaiting transplant.

This proposal mainly impacts adult heart candidates. The Committee does not anticipate this proposal will have a negative impact on pediatric candidates, and may even have a positive impact on pediatric access to heart transplant. Though the number of pediatric candidates is small and therefore more difficult to analyze, the TSAM analysis shows total increased transplant counts for pediatric candidates under the 6 urgency status with broader sharing scheme, and the transplant rate for pediatric status 1A candidates increased. The overall death counts also decrease slightly. The Committee's proposed changes to the pediatric donor allocation sequence (to accommodate the new six adult statuses) are also expected to ensure that pediatric candidates are not negatively impacted by this proposal and may experience a slight benefit in terms of allocation.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.

2. *Improve equity in access to transplants:* Revising the heart allocation system will provide more equitable access to transplants based on medical urgency and on geographic location. The proposal is primarily aligned with this strategic goal.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Waiting list mortality rates for adult heart candidates are expected to improve under the proposed policy, as candidates most in need of transplant will be transplanted more quickly and therefore not dying while waiting for a transplant. Overall post-transplant mortality may increase slightly as more urgent candidates are transplanted at increased rates.

4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.

5. *Promote the efficient management of the OPTN:* The proposed statuses may decrease the number of exception requests that are submitted to the regional review boards, because the new statuses incorporated into policy the conditions for many groups of candidates that previously applied for exceptions. Decreasing the number of exception requests will help the OPTN operate more efficiently by reducing staff time spent processing the requests, and reducing the amount of volunteer time required for regional review board members to review the requests.

How will the OPTN implement this proposal?

This proposal will require a significant level of effort to program the new status criteria and sharing schemes in UNet^{SM}. Prior to implementation, the OPTN will provide transplant programs with a timeframe in which to update current candidates' information in UNet^{SM} according to the new policy requirements. On the day of implementation, UNet^{SM} will allocate organs using the new information. According to existing policy, within 24 hours of the implementation date, transplant programs should verify that their candidates' information is up-to-date in UNet^{SM}, to ensure that their candidates are classified in the appropriate new urgency status. Candidates whose records are not updated by the time of implementation will appear in status 6 (or status 5 if the candidate is registered at the same transplant hospital for another organ).

Exceptions that are approved prior to implementation and exception requests that are in progress at the time of implementation will be ineffective upon implementation. Many of the exception requests are expected to be unnecessary upon implementation, because the proposed policy is intended to accommodate the conditions of many candidates who previously needed an exception.

The OPTN will ensure that waiting time accumulated under the old system will transition to the new system so that candidates already waiting will not be disadvantaged on the date of implementation. Waiting time will transfer and accumulate according to **Table 4**, below.

Table 4: Waiting Time Transfer and Accumulation

New Status	Waiting Time Calculated As
Status 1	Accumulated time at New Status 1 Plus accumulated time at Status 1A*
Status 2	Accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated Time at Status 1A*

New Status	Waiting Time Calculated As
Status 3	Accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A*
Status 4	Accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B
Status 5	Accumulated time at New Status 5 Plus accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B Plus accumulated Time at Old Status 2
Status 6	Accumulated time at New Status 6 Plus accumulated time at New Status 5 Plus accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B Plus accumulated Time at Old Status 2 (same as total Waiting Time minus any Inactive Time)

*Accumulated time a status 1A includes any pre-January 1999 status 1 time.

The OPTN will educate members prior to implementation to ensure that all members know how to transition their patients to the new system.

How will members implement this proposal?

Transplant Hospitals

Members will need to update data for candidates registered on the waiting list prior to full implementation. Within 24 hours of implementation, members will need to verify their candidates' information is correct, and reflects the new requirements in the proposed policy to ensure that their candidate is classified at the most appropriate status. Members will also need to submit more data than is currently required for each candidate during each status change or update at intervals defined in the proposed policy.

Feedback received from some commenters during both rounds of public comment suggested this change may impact transplant program costs, as broader sharing may increase the number and distance/time of additional heart fly outs and as some programs may need to hire more transplant surgeons to travel further to recover hearts from donors. Additional transplant center staff time to record data for additional transplant volume may be required.

OPOs

The proposed policy includes changes to the allocation sequence to require hearts to be shared to the DSA and Zone A combined for statuses 1 and 2. Feedback received from some commenters during both rounds of public comment suggested this change may impact OPO practices and costs. This impact may be mitigated by the current proposal, as the proposed allocation scheme is limited to DSA and Zone A, as compared with the original sharing scheme which also shared to Zone B.

Histocompatibility Laboratories

Since the proposal simply requires that CPRA data be reported, and does not mandate additional testing, it is unlikely that increased recurring cost to histocompatibility laboratories due to testing will be realized. In the case of increased testing, recurring costs account for additional antibody testing and crossmatching supplies for highly sensitized heart patients and any potential staff overtime hours to complete the additional work volume. While unlikely, increased volume in crossmatch and testing may require purchase of additional instrumentation to support the increase.

Will this proposal require members to submit additional data?

As explained above, the Committee considered creating a heart allocation score in lieu of proposing additional statuses, but could not do so due to the lack of necessary data in the OPTN data system. The Committee received feedback during the first round of public comment that some people would prefer the Committee develop a heart allocation score, or that they are supportive of the creation of a score in the future. The Committee learned lessons from its development of the lung allocation score (LAS) in the past, and recognizes that in order to effectively develop a score, the same data must be collected for all candidates at established intervals.

Presumably, like the LAS, the heart allocation score will weigh waiting list mortality risk against post-transplant survival risk. Therefore, the Committee identified various factors that published studies and clinical consensus find influence a candidate's risk of mortality on the waiting list or post-transplant mortality (**Exhibit C**). The Committee recognizes the list in **Exhibit C** may be over-inclusive, and therefore sought public comment on whether it is exhaustive or whether any data elements should be deleted for lack of predictive power or lack of feasibility for collecting the information on all candidates. The Committee also sought feedback on whether some data should be collected only on candidates supported by VADs.

Improved risk stratification and risk adjustment may also be achieved through enhanced data collection. The data currently reported to the OPTN do not provide adequate information to allow for more precise risk adjustment based on current practices. Risk influences transplant program behavior. Transplant programs that perceive a candidate as “high-risk” may be less likely to transplant the candidate to avoid a potentially poor post-transplant outcome. If risk adjustment is precise, transplant programs can make more informed decisions about the relative benefit or risk of transplanting a particular candidate. The SRTR may incorporate these new data into the risk adjustment models that inform the program specific reports.

Data that are currently collected on the Tiedi® forms will continue to be collected as it is currently performed. Additionally, the mechanical circulatory support device information that transplant programs report to the OPTN retrospectively when a candidate is removed from Waitlist will continue to be collected as it is currently.

How will members be evaluated for compliance with this proposal?

The proposed policy modifications will not affect the methods by which UNOS staff routinely review members, but the content of the review may change based on the proposed modifications.
UNOS staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to policy requirements and will continue to investigate potential policy violations.
At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Information reported on the adult status justification form is consistent with source documentation
- The candidate met the requirements for the qualifying criterion selected on the adult status justification form and any required sub-criteria
- The candidate's medical urgency status or qualifying criteria used to justify the status were updated in UNet^{SM} within 24 hours of a change in the candidate's medical condition to accurately reflect the change in condition

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

The Thoracic Committee will review waiting list and transplant data for all ages to ensure that this change in allocation serves its intended purpose without negatively impacting pre- or post-transplant outcomes for pediatric candidates/recipients. Outcomes in other populations may be assessed for unintended consequences as warranted; stratifications that may be considered include gender and race.

Since external factors and other changes in transplant policy can have an influence on the period following policy implementation, interpreting the apparent impact of this policy change based on “before vs. after” analysis must be done with caution.

Questions that will need to be answered as policy evaluation:

The following questions, and any others subsequently requested by the Committees, will guide the evaluation of the proposal after implementation.

- Have death rates for adult candidates on the heart waiting list decreased?
- Have transplant rates for adult candidates on the heart waiting list increased?
- Have post-transplant survival rates for adult heart recipients changed?
- Has the zonal distribution of heart transplants changed?
- Has the number of exception requests decreased?

- Has the heart utilization rate increased?

Data used to evaluate the proposal (Policy Performance Measures):
The following metrics, and any others subsequently requested by the Committee, will be used to evaluate the proposal. These metrics will be provided for the post-policy period, and compared to the pre-policy period, where possible. For pre- and post-policy comparisons involving medical urgency status, an approximate correspondence will be used: current status 1A compared to proposed statuses 1-3, and current status 1B compared to proposed tiers 4 and 5.

- Waiting list additions stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
- Waiting list death rates stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
- Waiting list transplant rates stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
- Transplants stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
  - Zone (DSA, Zone A, Zone B, etc.)
- Post-transplant patient survival stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
  - Zone (DSA, Zone A, Zone B, etc.)
- Exception requests stratified by:
  - Medical urgency status
  - Region
  - Medical urgency status within Region
- Utilization of deceased donor hearts stratified by:
  - Donor age
  - Region

Timeline for evaluation:
The initial data analysis will be performed after the policy has been in place for about 6 months. Data will be evaluated no more frequently than every 6 months for the first two years and annually thereafter until 5 years post-implementation. Timeline is subject to change based on the results.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

RESOLVED, that changes to Policies 3.7.B (Required Expedited Modifications of Waiting Time), 6.1 (Status Assignments and Update Requirements), 6.1.A (Adult Heart Status 1A Requirements), 6.1.B (Adult Heart Status 1B Requirements), 6.1.C (Adult Heart Status 2 Requirements), 6.2 (Status Updates), 6.3 (Adult and Pediatric Status Exceptions), 6.3.A (RRB and Committee Review of Exceptions), 6.3.B (Exceptions to Allocation for Sensitized Candidates), 6.4 (Waiting Time), 6.5.C (Sorting Within Each Classification), 6.5.D (Allocation of Hearts from Donors at Least 18 years Old), 6.5.E (Allocation of Hearts from Donors Less Than 18 Years Old), 6.5.F (Allocation of Heart-Lungs), Bylaws Appendix K.5 (Transition Plan during Long-term Inactivity, Termination, or Withdrawal), and Appendix M (Definitions), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

3.7.B Required Expedited Modifications of Waiting Time

An application for waiting time modifications must follow the procedures for expedited modifications of waiting time if it meets *any* of the following criteria according to *Table 3-5* below:

Table 3-5: Applications Requiring Expedited Modifications of Waiting Time

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
An error occurred in removing the candidate's waiting list record	The same organ	Time accrued under the previous registration and any time lost by the error.
An error occurred in registering, modifying, or renewing the candidate's waiting list record	Status 1 liver, pediatric ~~S~~status 1A heart, adult status 1, 2, 3, or 4 heart, or ~~P~~priority 1 pediatric lung	Any time lost by the error.
The candidate was removed from the waiting list for medical reasons, other than receiving a transplant	The same organ with the same diagnosis	Time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
An islet recipient has re-registered on the islet waiting list	An islet infusion	Any previously accrued waiting time according to *Policy 11.3.C: Islet Waiting Time Criteria*.
The candidate needs a second organ	Heart, liver, or lung	Modified waiting time for the second organ that includes the waiting time accrued for the first organ.

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
The candidate needs a second organ, routine alternative therapies are not possible, and the other transplant programs within the OPO and the OPO itself agree to the modified waiting time	Kidney, pancreas, or intestine	Modified waiting time for the second organ that includes the waiting time for the first organ.

Additionally, applications must meet any additional requirements outlined in the organ-specific allocation policies. If an application does not comply with the requirements of *Policy 3.7: Waiting Time Modifications*, then the OPTN Contractor will not implement the requested waiting time modifications or forward the application for review.

Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, including the name and signature of the candidate's physician or surgeon, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ-specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

6.1 Adult Status Assignments and Update Requirements

Each adult heart transplant candidate at least 18 years old at the time of registration is assigned a status that reflects the candidate's medical urgency for transplant. The candidate's transplant program must submit a heart status justification form to the OPTN Contractor to assign a candidate the status for which the candidate qualifies. Transplant programs must assign candidates on the waiting list that are not currently suitable for transplant to the inactive status.

~~Heart candidates at least 18 years old at the time of registration may be assigned *any* of the following:~~

~~• Adult status 1A~~
~~• Adult status 1B~~
~~• Adult status 2~~
~~• Inactive status~~

~~Heart candidates less than 18 years old at the time of registration may be assigned any of the following:~~

~~• Pediatric status 1A~~
~~• Pediatric status 1B~~
~~• Pediatric status 2~~
~~• Inactive status~~

~~A candidate registered on the waiting list before turning 18 years old remains eligible for pediatric status until the candidate has been removed from the waiting list.~~

If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must submit a new heart status justification form to the OPTN Contractor within 24 hours of the change in medical condition.

If a candidate's transplant program does not submit a heart status justification form or the status expires and the transplant program does not submit a new heart status justification form, the candidate is assigned to status 6, or status 5 if the candidate is registered for another organ.

When registering a candidate, the transplant program must submit to the OPTN Contractor *all* of the following clinical data:

- Hemodynamic assessment results
- Functional status or exercise testing results
- Heart failure severity or end organ function indicators
- Heart failure therapies
- Mechanical support
- Sensitization risk, including CPRA, peak PRA, and number of prior sternotomies
- Current diagnosis

These clinical data must be submitted every time the transplant program submits a justification form unless a test needed to obtain the data has not been performed since the last justification form was submitted. The transplant program must maintain source documentation for all laboratory values reported to the OPTN Contractor.

6.1.A Adult Heart Status ~~1A~~ 1 Requirements

To assign a candidate to adult status 1~~1A~~, the candidate's transplant program must submit a *Heart Status* 1~~1A~~ *Justification Form* to the OPTN Contractor. A candidate is not assigned to adult status 1~~1A~~ until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 1~~1A~~ if the candidate has at least *one* ~~*either*~~ of the following conditions ~~is met~~:

- Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO), according to *Policy 6.1.A.i* below.
- Is supported by a non-dischargeable, surgically implanted, non-endovascular biventricular support device according to *Policy 6.1.A.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) and has a life-threatening ventricular arrhythmia according to *6.1.A.iii* below.

6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by VA ECMO for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to VA ECMO support, *all* of the following are true within one 24 hour period:
  a. Systolic blood pressure less than 90 mmHg
  b. Cardiac index less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 if the candidate is supported by at least one inotrope
  c. Pulmonary capillary wedge pressure greater than 15 mmHg

- If hemodynamic measurements could not be obtained within 7 days prior to VA ECMO support, at least *one* of the following is true within 24 hours prior to VA ECMO support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet either of the criteria above will remain in this status for up to 7 days from submission of the *Heart Status 1 Justification Form*. After 7 days, the transplant program may apply to the regional review board (RRB) to extend the candidate at this status if the candidate remains supported by VA ECMO. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the extension request, the transplant program failed at weaning the candidate from VA ECMO as evidenced by at least *one* of the following:
   - Mean arterial pressure (MAP) less than 60 mmHg
   - Cardiac index less than 2.0 L/min/m^2
   - Pulmonary capillary wedge pressure greater than 15 mmHg
   - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by VA ECMO after 7 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular biventricular support device and must remain hospitalized because the device is not FDA-approved for out of hospital use.

This status is valid for up to 14 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form.*

6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation as evidenced by at least *one* of the following:

- Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias
- That the patient was not considered a candidate for other treatment alternatives,

such as ablation, by an electrophysiologist, and has experienced three or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 14 days that *both:*

1. Occurred in the setting of normal serum magnesium and potassium levels
2. Required electrical cardioversion despite receiving antiarrhythmic therapies

This status is valid for up to 14 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized on intravenous anti-arrhythmic therapy.

~~1. The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, or an affiliated Veteran's Administration (VA) hospital, and the candidate also meets at least *one* of the requirements in *Table 6-1* below.~~

~~**Table 6-1: Adult Status 1A Requirements for Candidates Currently Admitted to the Transplant Hospital**~~

~~If the candidate meets this condition:~~	~~Then adult status 1A is valid for:~~
~~Has one of the following mechanical circulatory support devices in place: • Total artificial heart (TAH) • Intra-aortic balloon pump • Extracorporeal membrane oxygenation (ECMO)~~	~~14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.~~
~~Requires continuous mechanical ventilation~~	~~14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the Status 1A registration.~~
~~Requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of left ventricular filling pressures. The OPTN Contractor will maintain a list of the OPTN-approved qualifying inotropes and doses.~~	~~7 days, and may be renewed for additional 7 day periods for each occurrence of an adult status 1A listing under this criterion for this candidate.~~

~~2. A candidate who is at least 18 years old at the time of registration, and may or may not be currently admitted to the transplant hospital, may be assigned adult status 1A if the candidate meets at least *one* of the requirements in *Table 6-2* below.~~

~~**Table 6-2: Adult Status 1A Requirements for Candidates- Current Hospitalization Not Required**~~

~~If the candidate meets this condition:~~	~~Then the status is valid for:~~
~~Has *one* of the following mechanical circulatory support devices in place: • Left ventricular assist device (LVAD) • Right ventricular assist device (RVAD) • Left and right ventricular assist devices (BiVAD)~~	~~30 days, and the candidate may be registered as adult status 1A for 30 days at any point after being implanted once an attending physician determines the candidate is medically stable. The 30 days do not have to be consecutive. However, if the candidate undergoes a procedure to receive another device, then the candidate qualifies for a new term of 30 days. Any 30 days granted by the new device would substitute and not supplement any time remaining from the previous adult status 1A classification.~~
~~Candidate has mechanical circulatory support and there is medical evidence of significant device-related complications including, but not limited to, thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias. A candidate's sensitization is not an acceptable device-related complication to qualify as adult status 1A. If a transplant program reports a complication that is not listed here, the registration will be retrospectively reviewed by the heart regional review board (RRB)~~	~~14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.~~

~~If the attending physician does not update the qualifications for adult status 1A registration when required according to *Tables 6-1* and *6-2* above, then the candidate's adult status 1A will expire and the candidate will be downgraded to adult status 1B.~~

6.1.B Adult Heart Status ~~1B~~2 Requirements

To assign a candidate to adult status 2 ~~status 1B~~, the candidate's transplant program must submit a *Heart Status 2* ~~*Status 1B*~~ *Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 2 ~~status 1B~~ until this form is submitted.

~~The candidate's transplant program may assign the candidate as adult status 1B i~~If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 2 if ~~and has~~ the candidate has at least *one* of the following ~~devices or therapies in place~~ conditions:

- Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), according to *Policy 6.1.B.i* below.
- Is supported by a total artificial heart (TAH), biventricular assist device (BiVAD), right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients, according to *Policy 6.1.B.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) that is malfunctioning, according to *Policy 6.1.B.iii* below.
- Is supported by a percutaneous endovascular circulatory support device, according to *Policy 6.1.B.iv* below.
- Is supported by an intra-aortic balloon pump (IABP), according to *Policy 6.1.B.v* below.

- Is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation according to *Policy 6.1.B.vi* below.

6.1.B.i Non-dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular LVAD, and must remain hospitalized because the device is not FDA-approved for out of hospital use.

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. After 14 days, the transplant program may apply to the RRB to extend the candidate's registration if the candidate remains supported by the non-dischargeable surgically implanted, non-endovascular LVAD. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the extension request, the transplant program failed at weaning the candidate from the non-dischargeable surgically implanted, non-endovascular LVAD as evidenced by at least *one* of the following:
   - Mean arterial pressure (MAP) less than 60 mmHg
   - Cardiac index less than 2.0 L/min/m^2
   - Pulmonary capillary wedge pressure greater than15
   - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the non-dischargeable surgically implanted, non-endovascular LVAD after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.ii Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or Dischargeable Ventricular Assist Device (VAD) for Single Ventricle Patients

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is supported by *any* of the following:

- A TAH
- An RVAD alone
- A BiVAD
- A VAD, for single ventricle patients only

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by an MCSD that is experiencing device malfunction as evidenced by *all* of the following:

1. Malfunction of at least one of the components of the MCSD
2. Malfunction cannot be fixed without an entire device replacement
3. Malfunction is currently causing inadequate circulatory support or places the candidate at imminent risk of device stoppage

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by a percutaneous endovascular mechanical circulatory support device without an oxygenator for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to percutaneous endovascular mechanical circulatory support, *all* of the following are true within one 24 hour period:
  a. Systolic blood pressure less than 90 mmHg
  b. Cardiac index less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 if the candidate is supported by inotropes
  c. Pulmonary capillary wedge pressure greater than 15 mmHg
- If hemodynamic measurements could not be obtained within 7 days prior to percutaneous endovascular mechanical support, at least *one* of the following is true within 24 hours prior to percutaneous endovascular mechanical circulatory support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. After 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the percutaneous endovascular circulatory support device. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the extension request, the transplant program failed at weaning the candidate from the acute percutaneous endovascular circulatory support device evidenced by at least *one* of the following:
   - Mean arterial pressure (MAP) less than 60 mmHg

- Cardiac index less than 2.0 L/min/m^2
- Pulmonary capillary wedge pressure greater than15 mmHg
- SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the percutaneous endovascular mechanical circulatory support device after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.v Intra-Aortic Balloon Pump (IABP)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by an IABP for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to IABP support, *all* of the following are true within one 24 hour period:
  a. Systolic blood pressure less than 90 mmHg
  b. Cardiac index less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or less than 2.0 L/min/m^2 if the candidate is supported by inotropes
  c. Pulmonary capillary wedge pressure greater than 15 mmHg
- If hemodynamic measurements could not be obtained within 7 days prior to IABP support, at least *one* of the following is true within 24 hours prior to IABP support:
  - CPR was performed on the candidate
  - Systolic blood pressure less than 70 mmHg
  - Arterial lactate greater than 4 mmol/L
  - AST or ALT greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of *the Heart Status 2 Justification Form*. After 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the IABP. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device
2. Within 48 hours prior to the extension request, the transplant program failed to wean the candidate from the IABP as evidenced by at least *one* of the following:
   - Mean arterial pressure (MAP) less than 60 mmHg
   - Cardiac index less than 2.0 L/min/m2
   - Pulmonary capillary wedge pressure greater than 15 mmHg
   - SvO_2 less than 50 percent measured by central venous catheter

The RRB will retrospectively review extension requests. If the candidate is still supported by the IABP after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.vi Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the

waiting list, is not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF episodes must have *both* of the following:

1. Occurred in the setting of normal serum magnesium and potassium levels
2. Required electrical cardioversion despite receiving intravenous antiarrhythmic therapies

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. This status can be extended by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

~~1. Left ventricular assist device (LVAD)~~
~~2. Right ventricular assist device (RVAD)~~
~~3. Left and right ventricular assist devices (BiVAD)~~
~~4. Continuous infusion of intravenous inotropes~~

~~Candidates that continue to qualify for adult status 1B may retain this status for an unlimited period and this status does not require any recertification, unless the candidate's medical condition changes as described in *Policy 6.2: Status Updates*.~~

6.1.C Adult Heart Status ~~2~~3 Requirements

~~If the candidate is at least 18 years old at the time of registration and does not meet the criteria for adult status 1A or 1B but is suitable for transplant, then the candidate may be assigned adult status 2.~~

~~The candidate may retain adult status 2 for an unlimited period and this status does not require recertification, unless the candidate's medical condition changes as described in *Policy 6.2: Status Updates*.~~

To assign a candidate to adult status 3, the candidate's transplant program must submit a *Heart Status 3 Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 3 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate adult status 3 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device and is exercising 30 days of discretionary time, according to *Policy 6.1.C.i* below.
- Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring, according to *Policy 6.1.C.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) with hemolysis, according to *Policy 6.1.C.iii* below.
- Is supported by an MCSD with pump thrombosis, according to *Policy 6.1.C.iv* below.
- Is supported by an MCSD and has right heart failure, according to *Policy 6.1.C.v* below.
- Is supported by an MCSD and has a device infection, according to *Policy 6.1.C.vi* below.
- Is supported by an MCSD and has bleeding, according to *Policy 6.1.C.vii* below.
- Is supported by an MCSD and has aortic insufficiency, according to *Policy 6.1.C.viii* below.
- Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 14 days, according to *Policy 6.1.C.ix below.*
- Is supported by a percutaneous endovascular circulatory support device after 14 days, according to *Policy 6.1.C.x below.*
- Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to *Policy 6.1.C.xi below.*

6.1.C.i Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by a dischargeable LVAD. OPTN Contractor maintains a list of OPTN-approved, qualifying devices.

The candidate may be registered as status 3 for 30 days at any point after being implanted with the dischargeable LVAD and once the attending physician determines the candidate is medically stable. Regardless of whether the candidate has a single transplant program registration or multiple transplant program registrations, the candidate receives a total of 30 days discretionary time for each dischargeable LVAD implanted across all registrations. Each day used by any of the transplant programs counts towards the cumulative 30 days.

The 30 days do not have to be consecutive and if the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.

6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the hospital that registered the candidate on the waiting list, and within 7 days prior to inotrope administration or while on inotropes meets *all* of the following:

1. Has *one* of the following:
   - Invasive pulmonary artery catheter
   - Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures
2. Is in cardiogenic shock, as evidenced by *all* of the following within one 24 hour period:
   a. Systolic blood pressure less than 90 mmHg
   b. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
   c. Cardiac index of *either*:
      - Less than 1.8 L/min/m^2 for candidates without inotropic or mechanical support within 7 days prior to inotrope administration
      - Less than 2.2 L/min/m^2 for candidates with inotropic or mechanical support
3. Is supported by *one* of the following:
   - A continuous infusion of *at least one* high-dose intravenous inotrope:
     - Dobutamine greater than or equal to 7.5 mcg/kg/min
     - Milrinone greater than or equal to 0.50 mcg/kg/min
     - Epinephrine greater than or equal to 0.02 mcg/kg/min
   - A continuous infusion of *at least two* intravenous inotropes:
     - Dobutamine greater than or equal to 3 mcg/kg/min
     - Milrinone greater than or equal to 0.25 mcg/kg/min
     - Epinephrine greater than or equal to 0.01 mcg/kg/min
     - Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form* if the candidate remains admitted to the hospital that registered the candidate on the waiting list, and the candidate remains supported by ongoing use of the qualifying inotrope therapy and meets *all* of the following:

1. O*ne* of the following hemodynamic monitoring:
   - Invasive pulmonary artery catheter
   - Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures
2. Within 48 hours prior to the extension request, must meet *either* of the following:
   - Cardiac index less than 2.2 L/min/m^2 on the current medical regimen
   - Failed attempt to wean the inotrope support documented by at least *one* of the following:
     - Cardiac index less than 2.2 L/min/m^2 during dose reduction
     - Increase in serum creatinine by 20 percent over the value immediately prior to, and within 24 hours of, inotrope dose reduction
     - Increase in arterial lactate to greater than 2.5 mmol/L
     - SvO_2 less than 50 percent measured by central venous catheter

6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by *both* of the following:

1. Two separate blood samples measured within 48 hours of each other confirming markers of active hemolysis as evidenced by *at least two* of the following criteria:
   - Lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
   - Plasma free hemoglobin greater than 20 mg/dL
   - Hemoglobinuria
2. Documentation of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is experiencing pump thrombosis as evidenced by at least *one* of the following:

- Visually detected thrombus in a paracorporeal ventricular assist device (VAD)
- Transient ischemic attack, stroke, or peripheral thromboembolic event, with non-invasive testing to exclude *both*:
  1. Intracardiac thrombus in all candidates
  2. Significant carotid artery disease in candidates with a neurological event

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and *both* of the following:

1. Requires treatment with at least *one* of the following therapies for at least 14 consecutive days:
   - Dobutamine greater than or equal to 5 mcg/kg/min
   - Dopamine greater than or equal to 4 mcg/kg/min
   - Epinephrine greater than or equal to 0.05 mcg/kg/min
   - Inhaled nitric oxide
   - Intravenous prostacyclin
   - Milrinone greater than or equal to 0.35 mcg/kg/min
2. Has, within 7 days prior to initiation of any of the therapies above, pulmonary capillary wedge pressure less than 20 mmHg and central venous pressure greater than 18 mmHg within one 24 hour period.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is experiencing a pump-related local or systemic infection, with *at least one* of the symptoms according to *Table 6-1: Evidence of Device Infection* below.

Table 6-1: Evidence of Device Infection

If the candidate has evidence of:	Then this status is valid for up to:
Erythema and pain along the driveline, with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and *either*: • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.

If the candidate has evidence of:	Then this status is valid for up to:
Bacteremia treated with antibiotics	42 days from submission of *the Heart Status 3 Justification Form*.
Recurrent bacteremia that recurs from the same organism within four weeks following antibiotic treatment to which the bacteria is susceptible	90 days from submission of *the Heart Status 3 Justification Form*.
Positive culture of material from the pump pocket of an implanted device	90 days from submission of *the Heart Status 3 Justification Form*.

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form*.

6.1.C.vii Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD, and meets the requirements according to *Table 6-2: Evidence of Mucosal Bleeding* below:

Table 6-2: Evidence of Mucosal Bleeding

If *all* of the following occurred:	Then this status is valid for *either*:
1. The candidate received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding 2. The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds 3. The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode	• Up to 14 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized for mucosal bleeding at least two times within the past six months • Up to 90 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized at least three times within the past six months

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form*.

6.1.C.viii Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI)

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI, with *all* of the following:

1. At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHg
2. Pulmonary capillary wedge pressure greater than 20 mmHg
3. New York Heart Association (NYHA) Class III-IV symptoms

This status is valid for up to 90 days from submission of *the Heart Status 3 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.ix VA ECMO after 14 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by VA ECMO, and has already assigned the candidate to status 1 according to *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* for 14 days.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.x Percutaneous Endovascular Circulatory Support Device after 14 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a percutaneous, endovascular circulatory support device, and has already assigned the candidate to status 2 according to *Policy 6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device* for 14 days.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.xi Intra-Aortic Balloon Pump (IABP) after 14 Days

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an IABP, and has already assigned the candidate to status 2 according to *Policy 6.1.B.v: Intra-Aortic Balloon Pump (IABP)* for 14 days.

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be extended by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.D Adult Heart Status 4 Requirements

To assign a candidate adult status 4, the candidate's transplant program must submit a *Heart Status 4 Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 4 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate adult status 4 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device (LVAD), according to *Policy 6.1.D.i* below.
- Is supported by inotropes without continuous hemodynamic monitoring, according to *Policy 6.1.D.ii* below.
- Is diagnosed with congenital heart disease, according to *Policy 6.1.D.iii* below.
- Is diagnosed with ischemic heart disease with intractable angina, according to *Policy 6.1.D.iv* below.
- Is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, according to *Policy 6.1.D.v* below.
- Is a re-transplant, according to *Policy 6.1.D.vi* below.

6.1.D.i Dischargeable Left Ventricular Assist Device (LVAD) without Discretionary 30 Days

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is supported by a dischargeable LVAD. The OPTN Contractor maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.ii Inotropes without Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is supported by a continuous infusion of a positive inotropic agent, and meets *all* of the following:

1. Cardiac index of less than 2.2 L/min/m^2 within 7 days prior to submission of the *Heart Status 4 Status Justification Form*
2. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
3. Requires at least *one* of the following intravenous inotropes:
    - Dobutamine greater than or equal to 3 mcg/kg/min
    - Milrinone greater than or equal to 0.25 mcg/kg/min
    - Epinephrine greater than or equal to 0.01 mcg/kg/min
    - Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.iii Congenital Heart Disease

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with a hemodynamically significant congenital heart disease. The OPTN Contractor maintains a list of OPTN-approved qualifying congenital heart disease diagnoses.

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.iv Ischemic Heart Disease with Intractable Angina

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with ischemic heart disease and has intractable angina, with *all* of the following:

1. Coronary artery disease
2. Canadian Cardiovascular Society Grade IV angina pectoris that cannot be treated by a combination of medical therapy, and percutaneous or surgical revascularization
3. Myocardial ischemia shown by imaging

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.v Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, with at least *one* of the following:

- Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy
- New York Heart Association (NYHA) Class III-IV symptoms with *either*:
  - Cardiac index less than 2.2 L/min/m^2
  - Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mmHg
- Ventricular tachycardia lasting at least 30 seconds
- Ventricular fibrillation
- Ventricular arrhythmia requiring electrical cardioversion
- Sudden cardiac death

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.D.vi Re-transplant

A candidate's transplant program may assign a candidate to adult status 4 if the candidate has a previous heart transplant, and there is evidence of International Society of Heart and Lung Transplantation (ISHLT) coronary allograft vasculopathy (CAV) grade 2-3, or New York Heart Association (NYHA) Class III-IV heart failure symptoms.

This status is valid for up to 90 days from submission of *the Heart Status 4 Justification Form*. After the initial 90 days, this status can be extended by the

transplant program every 90 days by submission of another *Heart Status 4 Justification Form*.

6.1.E Adult Heart Status 5 Requirements

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 5 if the candidate is registered on the heart waiting list, and is also registered on the waiting list for at least one other organ at the same hospital.

This status is valid for up to 180 days from submission of *the Heart Status 5 Justification Form* as long as the candidate is registered for another organ at the same hospital. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 5 Justification Form* as long as the candidate is registered for another organ at the same hospital.

6.1.F Adult Heart Status 6 Requirements

If the candidate is at least 18 years old at the time of registration and is suitable for transplant, then the transplant program may assign the candidate to adult status 6.

This status is valid for up to 180 days from submission of *the Heart Status 6 Justification Form* as long as the candidate remains suitable for transplant. After the initial 180 days, this status can be extended by the transplant program every 180 days by submission of another *Heart Status 6 Justification Form* as long as the candidate remains suitable for transplant.

6.2 Pediatric Status ~~Updates~~ Assignments and Update Requirements

Heart candidates less than 18 years old at the time of registration may be assigned any of the following:

- Pediatric status 1A
- Pediatric status 1B
- Pediatric status 2
- Inactive status

A candidate registered on the waiting list before turning 18 years old remains eligible for pediatric status until the candidate has been removed from the waiting list.

If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must submit a new heart status justification form to the OPTN Contractor within 24 hours of the change in medical condition.

6.~~1.~~1.2~~D~~A Pediatric Heart Status 1A Requirements

[*Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.*]

6.3 ~~Status~~ Adult and Pediatric Status Exceptions

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

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

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult ~~status 1A~~ status 1	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~~ status	RRBs retrospectively review requests for status 1~~Status 1A~~ exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively ~~• If no extension request is submitted, the candidate will be assigned adult status 1B~~
Adult status 2 ~~status 1B~~	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	RRBs retrospectively review requests for status 2~~Status 1B~~ exceptions	~~Indefinite~~ 14 days	~~• Not required as long as the candidate's medical condition remains the same.~~ • Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 3	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	RRBs retrospectively review requests for status 3 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 4	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 4 exceptions	90 days	• Require RRB approval for each successive 90 day period • RRB will review and decide extension requests retrospectively
Pediatric status 1A	• 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 1A exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB 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	RRBs retrospectively review requests for Status 1B exceptions	Indefinite	• Not required as long as candidate's medical condition remains the same

The candidate's transplant physician must submit a justification form to the OPTN Contractor with the requested status and the rationale for granting the status exception.

6.3.A RRB and Committee Review of Status Exceptions

The heart RRB reviews ~~all~~ applications for adult and pediatric status exceptions and extensions retrospectively. ~~If an adult status 1A exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status. If a pediatric status 1A or status 1B exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status, subject to automatic review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may review the RRB's decisions and rationale, and may refer any case to the Membership and Professional Standards Committee (MPSC) for further review.~~

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

6.3.A.i. RRB Appeals

If the RRB denies an exception or extension request, the candidate's transplant program must either appeal to the RRB within 1 day of receiving notification of the RRB denial, or assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the RRB denial.

6.3.A.ii Committee Appeals

If the RRB denies the appeal, the candidate's transplant program must within 1 day of receiving notification of the denied RRB appeal either appeal to the Thoracic Organ Transplantation Committee or assign the candidate to the status for which the candidate qualifies. If the Thoracic Committee agrees with the RRB's decision, the candidate's transplant program must assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If the transplant program does not assign the candidate to the status for which the candidate qualifies within 1 day of receiving notification of the denied Committee appeal, then the Committee will refer the case to the MPSC.

6.3.B Exceptions to Allocation for Sensitized Patients

An OPO ~~transplant program~~ may allocate a heart to sensitized candidates within its DSA out of sequence within a status as defined in *Policy 6.5: Heart Allocation Classifications and Rankings* if *all* of the following are true:

1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA).
2. All heart transplant programs and the OPO within the DSA agree to allocate a heart from a compatible deceased donor to the sensitized candidate.
3. The candidate's transplant program, all heart transplant programs, and the OPO within the DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception.

The sensitized candidate can only be prioritized ahead of candidates with the same status and within the same DSA. Sensitization alone does not qualify a candidate to be assigned any status exception as described in *Policy 6.3: Adult and Pediatric Status Exceptions* above.

6.4 Waiting Time

Waiting time for heart candidates begins when the candidate is first registered as an active heart candidate on the waiting list, and is calculated within each heart status.

If a candidate's status is upgraded, waiting time accrued while ~~registered at the~~ assigned to a lower status is not transferred to the higher status. Conversely, waiting time accrued while ~~registered~~ assigned at a higher status is transferred to a lower status if the candidate is ~~downgraded~~ assigned to a lower status.

Waiting time does not accrue while the candidate is inactive.

6.5 Heart Allocation Classifications and Rankings

6.5.C Sorting Within Each Classification

Candidates are sorted within each classification by the total amount of waiting time that the candidate has accumulated at that status, according to *Policy 6.4: Waiting Time*.

6.5.D Allocation of Hearts from Donors at Least 18 years Old

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-7* below.

Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Adult status 1 or pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA or Zone A	Adult status 2 and primary blood type match with the donor
4	OPO's DSA or Zone A	Adult status 2 and secondary blood type match with the donor
5	OPO's DSA	Adult status 3 or pediatric status 1B and primary blood type match with the donor
6	OPO's DSA	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
7	Zone B	Adult status 1 or pediatric status 1A and primary blood type match with the donor
8	Zone B	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
9	Zone B	Adult status 2 and primary blood type match with the donor
10	Zone B	Adult status 2 and secondary blood type match with the donor
11	OPO's DSA	Adult status 4 and primary blood type match with the donor
12	OPO's DSA	Adult status 4 and secondary blood type match with the donor
13	Zone A	Adult status 3 or pediatric status 1B and primary blood type match with the donor
14	Zone A	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
15	OPO's DSA	Adult status 5 and primary blood type match with the donor
16	OPO's DSA	Adult status 5 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
17	Zone B	Adult status 3 or pediatric status 1B and primary blood type match with the donor
18	Zone B	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
19	OPO's DSA	Adult status 6 or pediatric status 2 and primary blood type match with the donor
20	OPO's DSA	Adult status 6 and pediatric status 2 and secondary blood type match with the donor
21	Zone C	Adult status 1 or pediatric status 1A and primary blood type match with the donor
22	Zone C	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
23	Zone C	Adult status 2 and primary blood type match with the donor
24	Zone C	Adult status 2 and secondary blood type match with the donor
25	Zone C	Adult status 3 or pediatric status 1B and primary blood type match with the donor
26	Zone C	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
27	Zone A	Adult status 4 and primary blood type match with the donor
28	Zone A	Adult status 4 and secondary blood type match with the donor
29	Zone A	Adult status 5 and primary blood type match with the donor
30	Zone A	Adult status 5 and secondary blood type match with the donor
31	Zone A	Adult status 6 or pediatric status 2 and primary blood type match with the donor
32	Zone A	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
33	Zone D	Adult status 1 or pediatric status 1A and primary blood type match with the donor
34	Zone D	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
35	Zone D	Adult status 2 and primary blood type match with the donor
36	Zone D	Adult status 2 and secondary blood type match with the donor
37	Zone D	Adult status 3 or pediatric status 1B and primary blood type match with the donor
38	Zone D	Adult status 3 or pediatric status 1B and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
39	Zone B	Adult status 4 and primary blood type match with the donor
40	Zone B	Adult status 4 and secondary blood type match with the donor
41	Zone B	Adult status 5 and primary blood type match with the donor
42	Zone B	Adult status 5 and secondary blood type match with the donor
43	Zone B	Adult status 6 or pediatric status 2 and primary blood type match with the donor
44	Zone B	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
45	Zone E	Adult status 1 or pediatric status 1A and primary blood type match with the donor
46	Zone E	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
47	Zone E	Adult status 2 and primary blood type match with the donor
48	Zone E	Adult status 2 and secondary blood type match with the donor
49	Zone E	Adult status 3 or pediatric status 1B and primary blood type match with the donor
50	Zone E	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
51	Zone C	Adult status 4 and primary blood type match with the donor
52	Zone C	Adult status 4 and secondary blood type match with the donor
53	Zone C	Adult status 5 and primary blood type match with the donor
54	Zone C	Adult status 5 and secondary blood type match with the donor
55	Zone C	Adult status 6 or pediatric status 2 and primary blood type match with the donor
56	Zone C	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
57	Zone D	Adult status 4 and primary blood type match with the donor
58	Zone D	Adult status 4 and secondary blood type match with the donor
59	Zone D	Adult status 5 and primary blood type match with the donor
60	Zone D	Adult status 5 and secondary blood type match with the donor

Classification	**Candidates that are within the:**	**And are:**
61	Zone D	Adult status 6 or pediatric status 2 and primary blood type match with the donor
62	Zone D	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
63	Zone E	Adult status 4 and primary blood type match with the donor
64	Zone E	Adult status 4 and secondary blood type match with the donor
65	Zone E	Adult status 5 and primary blood type match with the donor
66	Zone E	Adult status 5 and secondary blood type match with the donor
67	Zone E	Adult status 6 or pediatric status 2 and primary blood type match with the donor
68	Zone E	Adult status 6 or pediatric status 2 and secondary blood type match with the donor

840

~~**Classification**~~	~~**Candidates that are within the:**~~	~~**And are:**~~
~~**1**~~	~~OPO's DSA~~	~~Adult or pediatric status 1A and primary blood type match with the donor~~
~~**2**~~	~~OPO's DSA~~	~~Adult or pediatric status 1A and secondary blood type match with the donor~~
~~**3**~~	~~OPO's DSA~~	~~Adult or pediatric status 1B and primary blood type match with the donor~~
~~**4**~~	~~OPO's DSA~~	~~Adult or pediatric status 1B and secondary blood type match with the donor~~
~~**5**~~	~~Zone A~~	~~Adult or pediatric status 1A and primary blood type match with the donor~~
~~**6**~~	~~Zone A~~	~~Adult or pediatric status 1A and secondary blood type match with the donor~~
~~**7**~~	~~Zone A~~	~~Adult or pediatric status 1B and primary blood type match with the donor~~
~~**8**~~	~~Zone A~~	~~Adult or pediatric status 1B and secondary blood type match with the donor~~
~~**9**~~	~~OPO's DSA~~	~~Adult or pediatric status 2 and primary blood type match with the donor~~
~~**10**~~	~~OPO's DSA~~	~~Adult or pediatric Status 2 and secondary blood type match with the donor~~
~~**11**~~	~~Zone B~~	~~Adult or pediatric status 1A and primary blood type match with the donor~~
~~**12**~~	~~Zone B~~	~~Adult or pediatric status 1A and secondary blood type match with the donor~~

Classification	Candidates that are within the:	And are:
13	Zone B	Adult or pediatric status 1B and primary blood type match with the donor
14	Zone B	Adult or pediatric status 1B and secondary blood type match with the donor
15	Zone A	Adult or pediatric status 2 and primary blood type match with the donor
16	Zone A	Adult or pediatric status 2 and secondary blood type match with the donor
17	Zone B	Adult or pediatric status 2 and primary blood type match with the donor
18	Zone B	Adult or pediatric status 2 and secondary blood type match with the donor
19	Zone C	Adult or pediatric status 1A and primary blood type match with the donor
20	Zone C	Adult or pediatric status 1A and secondary blood type match with the donor
21	Zone C	Adult or pediatric status 1B and primary blood type match with the donor
22	Zone C	Adult or pediatric status 1B and secondary blood type match with the donor
23	Zone C	Adult or pediatric status 2 and primary blood type match with the donor
24	Zone C	Adult or pediatric status 2 and secondary blood type match with the donor
25	Zone D	Adult or pediatric status 1A and primary blood type match with the donor
26	Zone D	Adult or pediatric status 1A and secondary blood type match with the donor
27	Zone D	Adult or pediatric status 1B and primary blood type match with the donor
28	Zone D	Adult or pediatric status 1B and secondary blood type match with the donor
29	Zone D	Adult or pediatric status 2 and primary blood type match with the donor
30	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
31	Zone E	Adult or pediatric status 1A and primary blood type match with the donor
32	Zone E	Adult or pediatric status 1A and secondary blood type match with the donor
33	Zone E	Adult or pediatric status 1B and primary blood type match with the donor
34	Zone E	Adult or pediatric status 1B and secondary blood type match with the donor

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~35~~	~~Zone E~~	~~Adult or pediatric status 2 and primary blood type match with the donor~~
~~36~~	~~Zone E~~	~~Adult or pediatric status 2 and secondary blood type match with the donor~~

6.5.E Allocation of Hearts from Donors Less Than 18 Years Old

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-8* below.

Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult status 1 and primary blood type match with the donor
4	OPO's DSA	Adult status 1 and secondary blood type match with the donor
5	OPO's DSA	Adult status 2 and primary blood type match with the donor
6	OPO's DSA	Adult status 2 and secondary blood type match with the donor
7	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor
8	OPO's DSA or Zone A	Pediatric status 1B and secondary blood type match with the donor
9	Zone A	Adult status 1 and primary blood type match with the donor
10	Zone A	Adult status 1 and secondary blood type match with the donor
11	Zone A	Adult status 2 and primary blood type match with the donor
12	Zone A	Adult status 2 and secondary blood type match with the donor
13	OPO's DSA	Adult status 3 and primary blood type match with the donor
14	OPO's DSA	Adult status 3 and secondary blood type match with the donor
15	OPO's DSA	Adult status 4 and primary blood type match with the donor
16	OPO's DSA	Adult status 4 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
17	OPO's DSA	Adult status 5 and primary blood type match with the donor
18	OPO's DSA	Adult status 5 and secondary blood type match with the donor
19	Zone A	Adult status 3 and primary blood type match with the donor
20	Zone A	Adult status 3 and secondary blood type match with the donor
21	Zone A	Adult status 4 and primary blood type match with the donor
22	Zone A	Adult status 4 and secondary blood type match with the donor
23	Zone A	Adult status 5 and primary blood type match with the donor
24	Zone A	Adult Status 5 and secondary blood type match with the donor
25	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
26	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
27	OPO's DSA	Adult status 6 and primary blood type match with the donor
28	OPO's DSA	Adult status 6 and secondary blood type match with the donor
29	Zone B	Pediatric status 1A and primary blood type match with the donor
30	Zone B	Pediatric status 1A and secondary blood type match with the donor
31	Zone B	Adult status 1 and primary blood type match with the donor
32	Zone B	Adult status 1 and secondary blood type match with the donor
33	Zone B	Adult status 2 and primary blood type match with the donor
34	Zone B	Adult status 2 and secondary blood type match with the donor
35	Zone B	Pediatric status 1B and primary blood type match with the donor
36	Zone B	Pediatric status 1B and secondary blood type match with the donor
37	Zone B	Adult status 3 and primary blood type match with the donor
38	Zone B	Adult status 3 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
39	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
40	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
41	OPO's DSA	Adult status 6 and primary blood type match with the donor
42	OPO's DSA	Adult status 6 and secondary blood type match with the donor
43	Zone C	Pediatric status 1A and primary blood type match with the donor
44	Zone C	Pediatric status 1A and secondary blood type match with the donor
45	Zone C	Adult status 1 and primary blood type match with the donor
46	Zone C	Adult status 1 and secondary blood type match with the donor
47	Zone C	Adult status 2 and primary blood type match with the donor
48	Zone C	Adult status 2 and secondary blood type match with the donor
49	Zone C	Pediatric status 1B and primary blood type match with the donor
50	Zone C	Pediatric status 1B and secondary blood type match with the donor
51	Zone C	Adult status 3 and primary blood type match with the donor
52	Zone C	Adult status 3 and secondary blood type match with the donor
53	Zone C	Adult status 4 and primary blood type match with the donor
54	Zone C	Adult status 4 and secondary blood type match with the donor
55	Zone C	Adult status 5 and primary blood type match with the donor
56	Zone C	Adult status 5 and secondary blood type match with the donor
57	Zone C	Pediatric status 2 and primary blood type match with the donor
58	Zone C	Pediatric status 2 and secondary blood type match with the donor
59	Zone C	Adult status 6 and primary blood type match with the donor
60	Zone C	Adult status 6 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
61	Zone D	Pediatric status 1A and primary blood type match with the donor
62	Zone D	Pediatric status 1A and secondary blood type match with the donor
63	Zone D	Adult status 1 and primary blood type match with the donor
64	Zone D	Adult status 1 and secondary blood type match with the donor
65	Zone D	Adult status 2 and primary blood type match with the donor
66	Zone D	Adult status 2 and secondary blood type match with the donor
67	Zone D	Pediatric status 1B and primary blood type match with the donor
68	Zone D	Pediatric status 1B and secondary blood type match with the donor
69	Zone D	Adult status 3 and primary blood type match with the donor
70	Zone D	Adult status 3 and secondary blood type match with the donor
71	Zone D	Adult status 4 and primary blood type match with the donor
72	Zone D	Adult status 4 and secondary blood type match with the donor
73	Zone D	Adult status 5 and primary blood type match with the donor
74	Zone D	Adult status 5 and secondary blood type match with the donor
75	Zone D	Pediatric status 2 and primary blood type match with the donor
76	Zone D	Pediatric status 2 and secondary blood type match with the donor
77	Zone D	Adult status 6 and primary blood type match with the donor
78	Zone D	Adult status 6 and secondary blood type match with the donor
79	Zone E	Pediatric status 1A and primary blood type match with the donor
80	Zone E	Pediatric status 1A and secondary blood type match with the donor
81	Zone E	Adult status 1 and primary blood type match with the donor
82	Zone E	Adult status 1 and secondary blood type match with the donor

Classification	Candidates that are within the:	And are:
83	Zone E	Adult status 2 and primary blood type match with the donor
84	Zone E	Adult status 2 and secondary blood type match with the donor
85	Zone E	Pediatric status 1B and primary blood type match with the donor
86	Zone E	Pediatric status 1B and secondary blood type match with the donor
87	Zone E	Adult status 3 and primary blood type match with the donor
88	Zone E	Adult status 3 and secondary blood type match with the donor
89	Zone E	Adult status 4 and primary blood type match with the donor
90	Zone E	Adult status 4 and secondary blood type match with the donor
91	Zone E	Adult status 5 and primary blood type match with the donor
92	Zone E	Adult status 5 and secondary blood type match with the donor
93	Zone E	Pediatric status 2 and primary blood type match with the donor
94	Zone E	Pediatric status 2 and secondary blood type match with the donor
95	Zone E	Adult status 6 and primary blood type match with the donor
96	Zone E	Adult status 6 and secondary blood type match with the donor

848

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's DSA or Zone A~~	~~Pediatric status 1A and primary blood type match with the donor~~
~~2~~	~~OPO's DSA or Zone A~~	~~Pediatric status 1A and secondary blood type match with the donor~~
~~3~~	~~OPO's DSA~~	~~Adult status 1A and primary blood type match with the donor~~
~~4~~	~~OPO's DSA~~	~~Adult status 1A and secondary blood type match with the donor~~
~~5~~	~~OPO's DSA or Zone A~~	~~Pediatric status 1B and primary blood type match with the donor~~
~~6~~	~~OPO's DSA or Zone A~~	~~Pediatric Status 1B and secondary blood type match with the donor~~
~~7~~	~~OPO's DSA~~	~~Adult Status 1B and primary blood type match with the donor~~

Classification	Candidates that are within the:	And are:
8	OPO's DSA	Adult Status 1B and secondary blood type match with the donor
9	Zone A	Adult Status 1A and primary blood type match with the donor
10	Zone A	Adult Status 1A and secondary blood type match with the donor
11	Zone A	Adult Status 1B and primary blood type match with the donor
12	Zone A	Adult Status 1B and secondary blood type match with the donor
13	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
14	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
15	OPO's DSA	Adult status 2 and primary blood type match with the donor
16	OPO's DSA	Adult status 2 and secondary blood type match with the donor
17	Zone B	Pediatric status 1A and primary blood type match with the donor
18	Zone B	Pediatric status 1A and secondary blood type match with the donor
19	Zone B	Adult status 1A and primary blood type match with the donor
20	Zone B	Adult status 1A and secondary blood type match with the donor
21	Zone B	Pediatric status 1B and primary blood type match with the donor
22	Zone B	Pediatric status 1B, secondary blood type match with the donor
23	Zone B	Adult status 1B and primary blood type match with the donor
24	Zone B	Adult status 1B and secondary blood type match with the donor
25	Zone A	Pediatric status 2 and primary blood type match with the donor
26	Zone A	Pediatric status 2 and secondary blood type match with the donor
27	Zone A	Adult status 2 and primary blood type match with the donor
28	Zone A	Adult status 2 and secondary blood type match with the donor
29	Zone B	Pediatric status 2, primary blood type match with the donor

Classification	Candidates that are within the:	And are:
30	Zone B	Pediatric status 2 and secondary blood type match with the donor
31	Zone B	Adult status 2 and primary blood type match with the donor
32	Zone B	Adult status 2 and secondary blood type match with the donor
33	Zone C	Pediatric status 1A and primary blood type match with the donor
34	Zone C	Pediatric status 1A and secondary blood type match with the donor
35	Zone C	Adult status 1A and primary blood type match with the donor
36	Zone C	Adult status 1A and secondary blood type match with the donor
37	Zone C	Pediatric status 1B and primary blood type match with the donor
38	Zone C	Pediatric status 1B and secondary blood type match with the donor
39	Zone C	Adult status 1B and primary blood type match with the donor
40	Zone C	Adult status 1B and secondary blood type match with the donor
41	Zone C	Pediatric status 2 and primary blood type match with the donor
42	Zone C	Pediatric status 2 and secondary blood type match with the donor
43	Zone C	Adult status 2 and primary blood type match with the donor
44	Zone C	Adult status 2 and secondary blood type match with the donor
45	Zone D	Pediatric status 1A and primary blood type match with the donor
46	Zone D	Pediatric status 1A and secondary blood type match with the donor
47	Zone D	Adult status 1A and primary blood type match with the donor
48	Zone D	Adult status 1A and secondary blood type match with the donor
49	Zone D	Pediatric status 1B and primary blood type match with the donor
50	Zone D	Pediatric status 1B and secondary blood type match with the donor
51	Zone D	Adult status 1B and primary blood type match with the donor

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~52~~	~~Zone D~~	~~Adult status 1B and secondary blood type match with the donor~~
~~53~~	~~Zone D~~	~~Pediatric status 2 and primary blood type match with the donor~~
~~54~~	~~Zone D~~	~~Pediatric status 2 and secondary blood type match with the donor~~
~~55~~	~~Zone D~~	~~Adult status 2 and primary blood type match with the donor~~
~~56~~	~~Zone D~~	~~Adult status 2 and secondary blood type match with the donor~~
~~57~~	~~Zone E~~	~~Pediatric status 1A and primary blood type match with the donor~~
~~58~~	~~Zone E~~	~~Pediatric status 1A and secondary blood type match with the donor~~
~~59~~	~~Zone E~~	~~Adult status 1A and primary blood type match with the donor~~
~~60~~	~~Zone E~~	~~Adult status 1A and secondary blood type match with the donor~~
~~61~~	~~Zone E~~	~~Pediatric status 1B and primary blood type match with the donor~~
~~62~~	~~Zone E~~	~~Pediatric status 1B and secondary blood type match with the donor~~
~~63~~	~~Zone E~~	~~Adult status 1B and primary blood type match with the donor~~
~~64~~	~~Zone E~~	~~Adult status 1B and secondary blood type match with the donor~~
~~65~~	~~Zone E~~	~~Pediatric status 2 and primary blood type match with the donor~~
~~66~~	~~Zone E~~	~~Pediatric status 2 and secondary blood type match with the donor~~
~~67~~	~~Zone E~~	~~Adult status 2 and primary blood type match with the donor~~
~~68~~	~~Zone E~~	~~Adult status 2 and secondary blood type match with the donor~~

6.5.F Allocation of Heart-Lungs

When a heart-lung potential transplant recipient (PTR) ~~candidate~~ is offered ~~allocated~~ a heart, the lung from the same deceased donor must be offered ~~allocated~~ to the heart-lung PTR ~~candidate~~.

When a heart-lung ~~candidate~~ PTR is ~~allocated~~ offered a lung, the heart from the same deceased donor must be offered ~~may only be allocated~~ to the heart-lung PTR according to *Table 6-9* below ~~candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart~~.

Table 6-9: Allocation of Heart-Lungs If PTR is Offered the Lung

When a heart-lung PTR in this geographic area is offered a lung:	The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all:	Within this geographic area:
OPO's DSA or Zone A	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	OPO's DSA or Zone A
Zone B	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone B
Zone C	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone C
Zone D	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone D
Zone E	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone E

The blood type matching requirements described in *Policy 6.5.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* applies to heart-lung candidates when the candidates appear on the lung match run.

OPTN Bylaws

Appendix K

K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal

When a member transplant hospital experiences long-term inactivity, withdraws its designated transplant program status, or its designated transplant program status is terminated, it must:

1. Immediately suspend organ transplantation for the transplant program.
2. Assist potential candidates and candidates in transferring to other designated transplant programs.
3. Provide a list to the OPTN Contractor of all of the transplant program's candidates on the waiting list at the time of long-term inactivity, withdrawal, or termination and update it throughout this process. The program should indicate on the list of each candidate if:

   - A candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision before they are removed from the waiting list.
   - A candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic status updates will be required that documents each candidate's transfer progress until the candidate is evaluated and accepted on the waiting list by

another transplant program or removed from the waiting list.

a. Expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN member transplant hospital.
b. Initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within 7 days of long-term inactivity, withdrawal, or termination. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time, or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates, if it is unable to meet these time periods.
c. Provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

    - For liver candidates, all Status 1A and 1B candidates must be transferred within 7 days of long-term inactivity, withdrawal, or termination, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates.
    - For lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates.
    - For kidney candidates, those whose PRA (measured or calculated) is over 80 percent should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates last.
    - For heart candidates, all pediatric ~~S~~status 1A and 1B and adult status 1, 2, 3 and 4 must be transferred within 7 days of long-term inactivity, withdrawal, or termination.
    - For multi-visceral organ transplant candidates, transfer must be completed within 30 days of long-term inactivity, withdrawal, or termination.
    - All active candidates should be transferred within 60 days of long-term inactivity, withdrawal, or termination without considering these guidelines.
    - The program must document and submit to the OPTN Contractor all efforts made for transfer of its candidates if it is unable to meet these deadlines.
    - Document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates.
    - Remove every transplant candidate from the transplant program's waiting list within 12 months of the program's long-term inactivity, withdrawal, or termination date.

A member that experiences long-term inactivity, withdrawal, or termination of a designated transplant program may still have the ability to temporarily provide care to transplant candidates, and provide follow-up care as necessary to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms through UNet^{SM}. Alternatively, transplant recipients may transfer care to another hospital.

Appendix M: Definitions

Regional Review Boards (RRBs)

Peer review panels established in each of the 11 regions to review all urgent status listings for ~~liver and~~ heart candidates. The RRB reviews justification forms submitted by each ~~center~~ transplant hospital documenting the severity of the candidate's illness and justifies the status at which the candidate is listed. ~~Liver RRBs review listings for all liver candidates in Status 1, special case exceptions for MELD/PELD liver candidates, and hepatocellular carcinoma (HCC) candidates. Thoracic~~ Heart RRBs review ~~listings~~ exception requests for ~~heart candidates in~~ pediatric ~~S~~status 1A and 1B heart candidates and adult status 1, 2, 3, and 4 ~~and special case~~ heart candidates ~~in pediatric 1B~~. These boards also consider appeals of cases initially refused for a particular medical urgency status.

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