

Public Comment Proposal

Amend Status Extension Requirements in Adult Heart Allocation Policy

OPTN Heart Transplantation Committee

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Amend Status Extension Requirements in Adult Heart Allocation Policy

<i>Affected Policies:</i>	<p>6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)</p> <p>6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device</p> <p>6.1.A.iii: Mechanical Circulatory Support Device (MCS) with Life Threatening Ventricular Arrhythmia</p> <p>6.1.C: Adult Heart Status 3 Requirements</p> <p>6.1.C.iv: Mechanical Circulatory Support Device (MCS) with Pump Thrombosis</p> <p>6.1.C.v: Mechanical Circulatory Support Device (MCS) with Right Heart Failure</p> <p>6.1.C.vi: Mechanical Circulatory Support Device (MCS) with Device Infection</p> <p>6.1.C.xiii: Mechanical Circulatory Support Device (MCS) with Life Threatening Ventricular Arrhythmia After 7 Days</p>
<i>Sponsoring Committee:</i>	Heart Transplantation
<i>Public Comment Period:</i>	August 3, 2021 – September 30, 2021

Executive Summary

In late 2018, the Organ Procurement and Transplantation Network (OPTN) implemented substantial changes to the adult heart allocation system. The modifications were intended to better stratify the most medically urgent heart transplant candidates, as well as, address mechanical circulatory support device (MCS) increased use and complications, among other objectives.¹

The 2018 modifications placed additional restrictions on the number of days candidates could stay at certain statuses and under certain criteria. Different levels of qualifying criteria were established for extending a status assignment. Some policies require a transplant program to submit detailed information about a candidate's medical condition during the time since initial waitlist assignment, while other policies only require transplant programs to submit another heart justification form.

Since implementation, transplant programs have questioned the policy requirements associated with extending a candidate's assignment at a status. Specifically, questions have been raised about whether new information documenting a candidate's medical condition is required if policy does not explicitly state the requirement for specific updated information used to determine original status.

¹ OPTN Thoracic Organ Transplantation Committee, *Proposal to Modify the Adult Heart Allocation System*, https://optn.transplant.hrsa.gov/media/1921/thoracic_adult_heart_allocation_modification_20160815.pdf (accessed June 23, 2021).

In 2021, the OPTN Heart Transplantation Committee (Committee)² reviewed an analysis of the use of extensions to increase the duration of a candidate’s assignment at a particular adult heart status. They noted that the findings suggested that extensions for certain statuses and criteria might be used more frequently than would be expected.

The Committee proposes improving the consistency of adult heart allocation policy. They intend to accomplish this by clarifying the criteria and circumstances under which a candidate is eligible to remain at an assigned status beyond the initial qualifying period. As part of this policy development process, additional policy areas were amended to address other emerging clinical concerns, including more specific requirements for candidates experiencing pump thrombosis.

This policy proposal supports the OPTN strategic goal of increasing equity in access to transplant. Clarifying how a candidate qualifies for an extension should help ensure that clinical statuses are accurately aligned to transplant candidates’ medical acuity.

² The OPTN Heart Transplantation Committee was officially created on July 1, 2020, and work before that time was performed by the OPTN Thoracic Organ Transplantation Committee. “Committee” in this proposal means either the Thoracic Committee of the Heart Committee depending on that point in time. OPTN, Notice of OPTN Policy, Bylaw, and Guidelines Changes, *Creation of OPTN Heart and Lung Committees*. <https://optn.transplant.hrsa.gov/media/3721/thoracic-split-policy-notice-march-2020.pdf> (Accessed June 23, 2021).

Background

This project continues the Committee’s previous efforts to address areas of improvement in heart allocation policy. A concern of the Committee is the potential “parking” of candidates at statuses for which they may be no longer qualified. Another concern relates to the different amounts and the timeliness of the information required to extend statuses. Under the current policy, certain statuses and criteria only require that a transplant program submit another justification form in order to extend a candidate’s assignment at a status. By contrast, other status criteria require submission of data collected after a candidate initially qualified. In such circumstances, a transplant program must demonstrate an ongoing need for the therapy by providing timely information about the candidate’s current medical condition. Specific extension request forms have been created in UNetSM for reporting the information.

To better identify the volume of candidates who might be impacted by the proposed changes, the Committee requested a data analysis of the number of candidates and extensions for certain statuses and criteria. The Committee considered the information in **Table 1** about the use of extensions per candidate to help guide their focus on which extension policies needed additional attention. The volume of extensions per candidate associated with the MCSD with Pump Thrombosis criteria was concerning to the Committee members and furthered their decision to move forward with changes to the policy language. The Committee also referenced the extensions per candidate when considering whether to increase or decrease the number of days a status assignment can be extended. They also considered the information as part of their decision-making about whether to add requirements that a candidate would need to meet in order to be eligible for an extension of their status.

Table 1: Extension Information by Status and Criteria

Status	Criteria	# of Candidates Ever-Waiting	# of Candidates Ever-Waiting Under Extension	Extension Forms Submitted	Extensions Per Candidate
1	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	99	25	51	0.51
2	Ventricular Tachycardia (VT) or Ventricular Fibrillation (VT)	95	20	31	0.33
3	MCSD with Pump Thrombosis	98	81	1,017	10.38
3	MCSD with Right Heart Failure	41	29	184	4.49
3	MCSD with Device Infection – Erythema	72	29	188	2.61
3	MCSD with Device Infection – Debridement	143	105	681	4.76
3	MCSD with Device Infection – Bacteremia	224	121	497	2.22
3	MCSD with Device Infection – Recurrent Bacteremia	26	5	12	0.46
3	MCSD with Device Infection –Positive Culture	27	10	24	0.89
Total		777	413	2,685	3.46

Note: Based on OPTN data as of January 15, 2021. Data subject to change based on future data submissions or corrections.

Source: OPTN Heart Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest*, January 20, 2021, p. 8.

The Committee also reviewed the information in **Table 2** regarding the average and median number of extensions, and days assigned by extension for the 413 candidates ever waiting at the statuses and criteria shown between October 18, 2018 and December 31, 2020 who had at least one extension. The amount of time assigned to one of the criteria by an extension provides context for how long candidates are spending at each criteria and serves as a function of the policy extension times, which differ across the criteria. The Subcommittee considered this information to help determine whether the number of days candidates were spending at a particular status and criteria by way of an extension appear appropriate based on the requirements. For example, *Policy 6.1.B.vi: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)* permits assignment for up to 14 days under an extension. As shown in the table, the median number of extensions under this criteria is one, and the median days spent was 12. This suggests that candidates assigned to *Policy 6.1.B.vi: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)* by extension are spending less than the full permissible 14 days.

Table 2: Extension Information by Status and Criteria

Status	Criteria	Average# of Extensions Used	Median# of Extensions Used	Length of Extension Currently in Policy	Average # of Days Extensions Were Used	Median # of Days Extensions Were Used
1	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2.0	1	7	20.92	8.0
2	Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)	1.6	1	14	15.75	12.0
3	MCS D with Pump Thrombosis	12.6	8	14	178.62	109.0
3	MCS D with Right Heart Failure	6.3	4	14	88.28	60.0
3	MCS D with Device Infection – Erythema	6.5	4	14	91.31	59.0
3	MCS D with Device Infection – Debridement	6.5	4	14	89.62	48.0
3	MCS D with Device Infection – Bacteremia	4.1	3	42	152.44	79.0
3	MCS D with Device Infection – Recurrent Bacteremia	2.4	2	90	148.00	100.0
3	MCS D with Device Infection – Positive Culture	2.4	2	90	146.80	82.5

Note: Based on OPTN data as of January 15, 2021. Data subject to change based on future data submissions or corrections.
 Source: OPTN Heart Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest*, January 20, 2021, p. 8.

On average, transplant programs submitted 12.6 extension requests per candidate under the MCS D with Pump Thrombosis criterion. Transplant programs submitted about six extensions, on average, for candidates assigned to criteria related to MCS D with right heart failure, device infection with erythema and device infection with debridement. It is important to note that candidates in more medically urgent statuses have much shorter median time to transplant, resulting in less need to submit as many extension forms.

Purpose

This proposal offers policy changes to address issues associated with extension requirements in certain policies and qualifying criteria. Among the issues are concerns regarding the inconsistency in extension requirements across adult heart allocation statuses and criteria. Additionally, the variability in the length of time provided under extension requirements across statuses and criteria also raised questions about how consistently candidates with similar medical urgencies are treated. The Committee also concluded that the policy addressing candidates with MCSD with Pump Thrombosis could be improved through changes to reflect current clinical practice better.

The Committee proposes the changes to ensure better that similarly situated heart candidates have equitable opportunities to receive an organ offer. The Committee also views the changes in tandem with their efforts approved by the OPTN Board of Directors in 2020 to address the use of Status 2 exceptions to better align candidates based in their medical urgencies.

Changes approved in 2016 by the OPTN Board of Directors established different categories for the amount and detail of information needed to extend a patient's status assignment. Some changes resulted in needing to document meeting medical criteria in order to extend, while others only required submission of another justification form without any updated information. The differences have led to members questioning what information is needed to comply. Consequently, Heart Committee members are concerned that some candidates are being assigned to statuses for longer periods of time than necessary.

The Committee also proposes clarifying the intent of *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis*. As written, the policy does not provide as much detail in describing the symptoms and treatments necessary for assigning a patient to this status, as certain other policies do. Furthermore, the policy does not identify a temporal relationship between when a patient experiences the symptoms and when the request for assignment at the status should occur. For example, according to Committee members, the policy could currently be interpreted as allowing a patient who had experienced a very remote event to qualify for this status (e.g. a stroke five years ago associated with ventricular assist device (VAD) issues, but no events since then).

The Eighteen-Month Monitoring of Heart Allocation report (Report) identified the number of waitlist additions and transplants that occurred while a candidate was assigned to a status using an extension form between October 18, 2018 and April 17, 2020 (19 months). During that time, a total of 5,750 candidates were added to the waitlist, and 1,052 individuals were transplanted while at status by extension. **Table 3** illustrates the number of waitlist additions and transplants under an extension form that occurred during that timeframe for the specified criteria:

Table 3: Number of Candidates Waiting and Transplant Recipients by Certain Adult Heart Policies and Criteria

Policy	Status and Qualifying Criteria	Individuals on Waitlist as of 12/16/2020	Waitlist Additions ^a	Transplants of Individuals at Status by Extension ^a
<i>Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device</i>	Status 1, Criteria 2	0	39	10
<i>Policy 6.1.B.vi: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)</i>	Status 2, Criteria 2	1	37	13
<i>Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis</i>	Status 3, Criteria 4	17	15	17
<i>Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure</i>	Status 3, Criteria 5	5	2	7
<i>Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection</i>	Status 3, Criteria 6	59	107	69
TOTAL		82	200	116

^a Waitlist additions and transplants occurred between 10/18/2018 and 04/17/2020.

Source: "Individuals on waitlist as of 12/16/2020" - Based on OPTN data on December 16, 2020; Data are subject to change based on future data submissions or corrections. Waitlist additions and transplants - OPTN Heart Committee, "Eighteen-Month Monitoring of Heart Allocation," October 29, 2020, table 2 and table 7.

The three Status 3 policies shown in the table account for 124 candidates added to the waiting list, approximately 18 percent of the 698 total additions made during that time. In addition, the 124 candidates are likely an underestimate of the total number because waitlist additions do not account for those patients who were initially listed at a less medically urgent status, but who are later assigned to Status 3 because they become sicker. For instance, most VAD patients are initially listed as Status 4; however, VAD patients who experience complications typically transition to one of the criteria under Status 3.

Additionally, candidates listed at Status 3 experienced large variability in median time to transplant depending on the criterion to which they are assigned.³ This suggests that not all candidates assigned to Status 3 are perceived as having the same medical urgency. (It is important to note that some of the Status 3 criteria have small sample sizes, and therefore the estimates may be less precise.) **Table 4** illustrates that MCSD with Pump Thrombosis, MCSD with Right Heart Failure, and MCSD with Pump Infection all have longer median days to transplant than the other Status 3 criteria. Finally, the number of transplants that occurred when a candidate was at Status 3 by extension accounted for approximately 33 percent of all transplants of Status 3 candidates. Based on these considerations and the potential for candidate "parking," the Heart Committee proposes several policy changes.

³ OPTN Heart Transplantation Committee, "Eighteen-Month Monitoring of Heart Allocation," October 29, 2020, Figure 28.

**Table 4: Median Days to Transplant for Adult Status 3 Candidates
Between October 18, 2018 and April 17, 2020**

Criteria	Median Days to Transplant
MCSD with Pump Thrombosis	236
MCSD with Right Heart Failure	162
MCSD with Infection	91
LVAD	84
MCSD with Aortic Insufficiency	61
Median for All Status 3 Candidates Waiting Before Transplant	28
Exception	22
Multiple / Single High Dose Inotropes and Hemodynamic Monitoring	16
MCSD with Hemolysis	10

Note: MCSD with Mucosal Bleeding was not included in the 18-month monitoring report because the sample size was too small. Source: OPTN Heart Committee, "Eighteen-Month Monitoring of Heart Allocation," October 29, 2020, Table 10: Median Days to Transplant by Medical Urgency and Era, p. 56 and Figure 28: Median Days to Transplant by Criteria within Medical Urgency Status Post-Implementation, p. 57.

Clarifying Extension Requirements to Improve Adult Heart Allocation Policy Consistency

Specific requirements listed with extension language are presumed to be all the requirements necessary to meet eligibility. Phrased differently, a candidate does not have to meet requirements that are not explicitly specified as part of the extension language.⁴ The consensus of the Committee was that policy should be amended to clarify that certain requirements would apply universally when seeking an extension of a candidate’s status assignment. The interpretation that a transplant program could extend a candidate’s time assigned to a particular status by simply submitting another heart status justification form concerned members of the Committee.⁵

As discussed, to extend a candidate’s Status 1 assignment under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device*, a transplant program is only required to extend the Heart Justification from within UNetSM for the candidate to be assigned at Status 1 for another seven days. Under the circumstances, a transplant program does not need to demonstrate that the candidate re-meets the initial qualifying criteria to extend. Nor does a transplant program have to provide objective evidence demonstrating that the candidate continues to meet the established criteria.

Table 5 identifies the policy requirements a Status 1 candidate must meet to have his or her assignment extended. *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* includes very specific language detailing the “objective evidence” a transplant program must provide to the regional review board (RRB) when requesting an extension. The evidence includes information that the candidate demonstrated a contraindication to support from a durable device and that the program failed to wean the candidate from VA ECMO as evidenced by hemodynamic data associated with a candidate still requiring support from the device.

⁴ OPTN Thoracic Committee, Meeting minutes from April 17, 2019, https://optn.transplant.hrsa.gov/media/2960/20190417_thoracic_minutes.pdf (access June 22, 2021).

⁵ OPTN Thoracic Heart Subcommittee, Meeting minutes from June 27, 2019, https://optn.transplant.hrsa.gov/media/3307/20190627_thoracic_heart-subcommittee_meeting-minutes.pdf (accessed June 22, 2021).

However, continuing a candidate’s Status 1 assignment based on either of the other criteria is less burdensome. Extending a candidate assigned to Status 1 under the requirements found in *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* only requires submission of another *Heart Status 1 Justification Form*. However, for a Status 1 candidate under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Arrhythmia*, the candidate must still be hospitalized in addition to submitting a *Heart Status 1 Justification Form*.

Table 5: Policy Requirements Associated With Extending an Adult Heart Candidate’s Assignment to Status 1

Policy	Requirements to extend a candidate’s stay at Status 1
<p><i>6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)</i></p>	<p>Every 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.</p> <p>The transplant program must provide to the RRB objective evidence of both of the follow:</p> <ol style="list-style-type: none"> 1. The candidate demonstrated a contraindication to being supported by a durable device 2. Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from VA EMCO as evidenced by at least one of the following: <ol style="list-style-type: none"> a. Mean arterial pressure (MAP) less than 60 mmHg b. Cardiac index less than 2.0 L/min/m² c. Pulmonary capillary wedge pressure greater than 15 mmHg d. SvO₂ less than 50 percent measured by central venous catheter <p>The RRB will retrospectively review extension requests.</p>
<p><i>6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device</i></p>	<p>This status can be extended by the transplant program every 7 days by submission of another <i>Heart Status 1 Justification Form</i>.</p>
<p><i>6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Arrhythmia</i></p>	<p>This status can be extended by the transplant program every 14 days by submission of another <i>Heart Status 1 Justification Form</i> if the candidate remains hospitalized on continuous intravenous antiarrhythmic therapy.</p>

Proposal

The Committee proposes clarifying that certain policies require demonstrating a candidate continues meeting certain criteria in order to extend the assignment at the status. The Committee also proposes changing some of the initial qualifying timeframes and extension timeframes to better align them within statuses and/or medical urgencies as appropriate. Finally, the Committee proposes revising policy addressing MCSDs with pump thrombosis to reflect better the medical conditions patients experience and the associated treatments.

Clarifying Extension Requirements to Improve Adult Heart Allocation Policy Consistency

The OPTN Heart Committee proposes amending adult heart allocation policy to ensure better that transplant programs demonstrate that a candidate continues to meet eligibility criteria in order to remain in the assigned status beyond the initial qualifying timeframe. Requiring that a candidate meet appropriate criteria to extend his or her stay at a status promotes equity in access to transplant because it better aligns the candidate's current medical urgency with the appropriate heart status. The proposed changes also seek to make policy more consistent by introducing similarly detailed criteria to extend, where current policies are more open-ended.

The consensus of the Committee was to include a hospitalization reference to ensure consistency across the three Status 1 criteria. The members agreed that this status needs to be reserved for the most medically urgent candidates. They also discussed whether all Status 1 criteria should require a transplant program to continually prove a candidate's urgency through the provision of current data. While a patient assigned to any of the three Status 1 criteria is likely to be hospitalized when receiving treatment, the current policy language addressing the extension criteria does not explicitly state that a candidate must remain hospitalized to extend the assignment. In order to extend a candidate's Status 1 assignment under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia*, the candidate must remain "hospitalized on continuous intravenous antiarrhythmic therapy." The Committee also proposes adding language to policies 6.1.A.i and 6.1.A.ii clearly stating that a candidate must remain hospitalized in order to qualify for a status extension.

To promote consistency, the Committee is proposing additional changes to *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia*. A candidate who no longer qualifies for status under the criterion would likely need to be assigned to Status 6, unless the candidate meets another status by standard criteria. The Committee agreed that Status 6 is not necessarily an appropriate assignment for such candidates based on their medical condition. It was noted that such candidates are stabilized, but not ready for outpatient care that would align them with Status 4 criteria. Instead, candidates experiencing these circumstances are more aligned with the Ventricular Assist Device (VAD) complications addressed in Status 3. Furthermore, not having a specific status for such candidates to transition to could be contributing to the number of exception requests submitted for Status 1, according to the Committee. To address the shortcoming, the Committee proposes adding a new criterion within Status 3 that would allow for transplant programs to transition a candidate who no longer is eligible for Status 1 assignment under *Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia*. The Committee modeled the proposed policy on existing Status 3 language for candidates transitioning from Status 1 under the *Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)*. Creating a Status 3 "landing spot" for such candidates provides transplant programs with an alternative that more closely aligns with the candidate's medical condition than Status 6. Moreover, it should encourage transplant programs to transition such candidates to Status 3 instead of continuing to extend them at Status 1 when that level of priority may no longer be medically appropriate.

Currently, a transplant program can extend a candidate's assignment to Status 3 under *Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection* by submitting another Heart Status 3 Justification Form. The program is not required to provide any additional information demonstrating that the candidate continues meeting any of the criteria associated with the Status. After considering

the circumstances, the Committee determined that it would be appropriate to require a candidate to continue meeting the criteria he or she initially qualified under and that the candidate experienced the condition within the timeframe associated with those criteria in policy. The Committee also proposes amending the extension requirement to include the current use of IV antibiotics to treat the candidate’s condition.

In addition to clarifying the policy language defining extension criteria, the Committee proposes changing the number of days a candidate can be assigned to an adult heart status initially and by extension. The proposed changes are identified in **Table 6**. As previously mentioned, the Committee members agreed that the Status 1 criteria should reflect the same number of days for an extension to reflect the medical urgency of the status. The Committee also determined that extending the number of days for MCSD with Pump Thrombosis and Right Heart Failure were based appropriately on a mixture of medical urgency and the previous use of extensions.

Table 6: Proposed Changes to Number of Days Assigned at Status

Status	Policy	Current # of Days Assignment Is Valid for Under Initial Request	Proposed # of Days Assignment Is Valid for Under Initial Request	Current # of Days Assignment Is Valid for Under Extension Request	Proposed # of Days Assignment Is Valid for Under Extension Request
1	6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia	14	7	14	7
3	6.1.C.iv: MCSD with Pump Thrombosis	14	30	14	90
3	6.1.C.v: MCSD with Right Heart Failure	14	14	14	90

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

It is the Committee’s consensus that *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis* is vague and does not provide an appropriate timeframe for signaling when the candidate was impacted by the condition. Additionally, as shown previously in Table 2, transplant programs submitted, on average, 12 extensions per candidate assigned to the MCSD with Pump Thrombosis criterion.

It is proposed that the policy can be improved by clarifying the timing of the event and submission of the request for the status. For instance, a transplant program could request that a candidate be assigned at Status 3 under this criterion even if the candidate had experienced a qualifying requirement, such as a stroke, years prior to submission of the Adult Heart Status 3 Justification Form. Based on the current policy language, such a candidate meets the standard requirements. The policy modification increases

the granularity of the standard criteria and establishes a temporal relationship between a candidate experiencing the identified symptoms and receiving treatment in the hospital.

To make the policy more detailed, the revisions focus on the suspected pump thrombosis symptoms that are likely to occur and the therapies used to treat such symptoms. The Committee members used their collective experience in treating such patients to guide their determinations. They agreed that adding specificity to the symptoms and treatments would make the criterion more consistent with similar Status 3 criteria. The changes should assist transplant programs with identifying whether a candidate truly meets the intended requirements. The Committee discussed that in order for a candidate to qualify for Status 3 using this criterion, at least one of the criteria describing the symptoms of pump thrombosis had to be met. Additionally, there was consensus that hospitalization is an appropriate requirement for assignment at Status 3 if a candidate is experiencing pump thrombosis, but seeking transplantation rather than having the pump replaced.

The Committee debated what would be the appropriate number of days to provide under an extension. Currently, the status is valid for up to 14 days for both the initial assignment and the extension. The Committee acknowledged that it is time consuming to determine whether a candidate is best served by a transplant rather than a pump replacement or other type of treatment. As a result, they did not want to propose a timeframe that would unnecessarily restrict a transplant program's ability to make a judicious decision. The Committee also considered the large volume of extensions used for these patients. When considering these changes, the Committee was reminded that an objective of this status extension project was to ensure that the criteria are fairer and not make it more difficult for candidates to be listed at Status 3. Based on these and other factors, the Committee decided to propose increasing the initial qualifying period from 14 to 30 days, and the extension timeframe from 14 to 90 days. By extending the timeframes, the proposal may also reduce the use of extensions for candidates experiencing pump thrombosis.

NOTA and Final Rule Analysis

The Heart Committee developed the policy proposal under the authority of the OPTN Final Rule, which states, "The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation of cadaveric organs... ." ⁶ This proposal seeks to clarify and make more consistent adult heart allocation policies for extending a candidate's assignment to a certain status and criteria.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with § 121.8." ⁷ This proposal is consistent with § 121.8 because it:

- **Is based on sound medical judgment.** ⁸ This proposal recommends several evidence-based policy changes. The recommendations rely on the medical judgment of the Committee members who based their decisions on OPTN data analyses and their collective clinical experience in treating heart transplant candidates. ⁹

⁶ 42 C.F.R. § 121.4(a)(1)

⁷ *Id.*

⁸ 42 C.F.R. § 121.8(a)(1)

⁹ OPTN Heart Committee, *Review of Extensions and Time Spent under Extension at Heart Statuses/Criteria of Interest*, January 20, 2021, p. 8.

- **Is seeking to achieve the best use of donated organs.**¹⁰ One of the best uses of a donated organ is for it to be transplanted according to medical urgency. The Committee’s proposed changes to the extension language in adult heart policy are intended to ensure that a candidate’s correct medical urgency designation, as indicated by their urgency status, is accurately maintained and used for prioritization.
- **Is specific for each organ**¹¹, in this case heart.
- **Is designed to promote access to transplantation.**¹² The proposed changes seeks to ensure that similarly situated candidates have equitable opportunities to receive an organ offer. The proposal does this by clarifying extension criteria to make it more consistent for candidates across all statuses, as well as within the statuses.

The changes recommended by the Committee also preserve the ability of a transplant program to decline an offer or not to use the organ for a potential recipient.¹³

This public comment proposal addresses certain aspects of the Final Rule listed above, and the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs.¹⁴
- Shall be designed to avoid futile transplants.¹⁵
- Shall be designed to promote the efficient management of organ placement.¹⁶
- Shall not be based on the candidate’s place of residence or place of listing.¹⁷

The Final Rule requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.¹⁸ During their discussions, the Committee considered whether any particular patient groups would be treated less favorably under the proposed policy changes. Under the proposed policy changes, some adult heart candidates will no longer qualify for extensions. However, the Committee is not recommending a transition procedure because their proposed changes are targeted specifically at making the extension requirements more consistent, and thus fairer, for all adult heart patients. It is proposed that when the policy changes are implemented, a candidate assigned to a status by extension will be allowed to complete the timeframe associated with the extension. However, at the end of the timeframe, the candidate’s transplant program would need to submit a new heart justification form, even if the candidate qualified under the new policy criteria. The action will be needed to accommodate system programming changes.

The OPTN proposes collecting additional data on heart candidates that qualify for the new status 3 criteria under the authority of the OPTN Final Rule, which requires the OPTN to: “(i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants; (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients; [and] (iii)

¹⁰ 42 C.F.R. § 121.8(a)(2)

¹¹ 42 C.F.R. § 121.8(a)(4)

¹² 42 C.F.R. § 121.8(a)(5)

¹³ 42 C.F.R. § 121.8(a)(3)

¹⁴ 42 C.F.R. § 121.8(a)(5)

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ 42 C.F.R. § 121.8(a)(8)

¹⁸ 42 C.F.R. § 121.8(d)(1)

Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested...”¹⁹ As a result of the creation of the new status 3 criteria, the OPTN will be collecting additional data on heart candidates that qualify for that status in the WaitlistSM application via the Heart Status Justification Form.

Implementation Considerations

Member and OPTN Operations

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Operations affecting Transplant Hospitals

This proposal will require transplant program staff to become familiar with updated OPTN data collection forms requirements for assigning a candidate to certain adult heart statuses, and potentially extending a candidate’s stay at some statuses. Transplant programs will need to familiarize themselves with changes to the adult heart justification forms. The forms will be updated to reflect the changes resulting in revised criteria and permissible lengths of stay at statuses.

Operations affecting the OPTN

The proposed policy changes are likely to result in the need for IT programming changes. For example, adding policy requirements to extend a candidate’s status will require that those requirements also be added, in some way, to the existing heart justification forms. As a result, additionally programming will be needed, at least initially.

The Committee is aware that by adding extension criteria, there may be an unintended increase in the number of exceptions submitted by transplant programs. The members indicated that the Regional Review Boards probably have the capacity to address such an increase, at least initially. The OPTN will monitor the number of requests for potential changes in volume.

Projected Fiscal Impact

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

¹⁹ 42 C.F.R. § 121.11(a)(1)(i)-(iii)

Projected Impact on the OPTN

This project is expected to have a large impact on the OPTN, primarily related to the changes associated with the adult heart justification forms. The potential exists that the resource estimate will be reduced as programming requirements become more refined.

Projected Impact on Transplant Hospitals

There is an expected minimal impact for transplant hospitals. The proposed modifications to the status extension requirements will require minimal staff training but will not alter existing processes and workflows or require new data collection.

Projected Impact on Histocompatibility Laboratories

There is no expected impact for histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is no expected impact for OPOs.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”²⁰

This proposal will not change the current routine monitoring of OPTN members. At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in UNetSM to justify a candidate's status are consistent with documentation in the candidate's medical record.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”²¹ This policy will be formally evaluated at approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available (Appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy. Timeline is subject to change based on the results. Data will be presented in tabular and graphical form as appropriate.

²⁰ 42 CFR §121.8(a)(7)

²¹ 42 CFR §121.8(a)(6)

The following metrics stratified by criteria within medical urgency status, and any others subsequently requested by the Committee, will be evaluated:

- The number and percent of waitlist additions
- The number and percent of transplants
- The number of initial and extension forms submitted
- The number of adult heart candidates ever waiting at specific medical urgency criteria
- The number of adult heart candidates ever waiting with at least one extension at the specific medical urgency criteria of interest
- Minimum, maximum, average and median number extensions (consecutive and non-consecutive) submitted for the specific medical urgency criteria of interest
- The average number of days spent at each of the medical urgency criteria of interest for candidates ever waiting at medical urgency criteria of interest

Conclusion

This proposal represents an effort on the part of the Heart Transplantation Committee to address issues with the extension language in adult heart allocation policy. The proposed changes focus on clarifying the requirements for extending a candidate's assignment at certain statuses and certain criteria. In most cases this involves adding language stating that a candidate needs to remain hospitalized following the initial assignment and/or still be receiving treatment for the initial qualifying condition, such as intravenous antibiotics. In another effort to improve consistency, the Committee is proposing changes to the number of days a candidate is eligible for assignment at certain status 1 and 3 criteria under both the initial and extension qualifying periods. The Committee members also agreed that a candidate who no longer meets the requirements for assignment under *Policy 6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia* should not be required to be reassigned at Status 6. To remedy the discrepancy, the Committee is proposing a new Status 3 criterion to help candidates transition to a more appropriate status based on their medical urgency. Finally, the Committee proposes clarifying *Policy 6.1.C.iv: MCSD with Pump Thrombosis* to better address the medical conditions and treatments the criterion is intended to address.

The Committee is requesting feedback about the following:

- Should the proposed changes to *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis* include a temporal relationship aligning when a patient experiences the medical conditions described and when the treatments are provided?
- Are the medical conditions and treatments included in the proposed changes to *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis* clearly described so that they may be easily understood and consistently interpreted by transplant program staff?
- Is Status 3 the appropriate status to transition a patient who was assigned to, but no longer meets, the eligibility criteria established for *Policy 6.1.A.iii*?
- Are there other requirements and/or criteria related to extending a candidate's assignment at an adult heart status that are unclear in terms of what information must be submitted?
- Are there other requirements and/or criteria related to extending a candidate's assignment at an adult heart status that are inconsistent in terms of treating patients with similarly situated medical urgencies?
- Should all adult heart policies require submission of objective evidence of a candidate's medical condition demonstrating a continued need for the established therapy in order to extend the candidate's assignment to the status?

- Should the Committee have considered changes to extension requirements / criteria in other specific adult heart policies? If yes, which policies and why?

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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 7 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 7 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized.

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 147 days that *both*:
 1. Occurred in the setting of normal serum magnesium and potassium levels
 2. Required electrical cardioversion despite receiving continuous intravenous antiarrhythmic therapies

This status is valid for up to 147 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 147 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized on continuous intravenous antiarrhythmic therapy.

55 After 7 days, if the candidate remains hospitalized and the transplant program does
 56 not request an extension, then the transplant program may assign the candidate to
 57 status 3.

58 59 **6.1.C Adult Heart Status 3 Requirements**

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

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

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- 68 • Is supported by a dischargeable left ventricular assist device and is exercising 30 days of
 69 discretionary time, according to *Policy 6.1.C.i* below.
- 70 • Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic
 71 monitoring, according to *Policy 6.1.C.ii* below.
- 72 • Is supported by a mechanical circulatory support device (MCS) with hemolysis, according
 73 to *Policy 6.1.C.iii* below.
- 74 • Is supported by an MCS with pump thrombosis, according to *Policy 6.1.C.iv* below.
- 75 • Is supported by an MCS and has right heart failure, according to *Policy 6.1.C.v* below.
- 76 • Is supported by an MCS and has a device infection, according to *Policy 6.1.C.vi* below.
- 77 • Is supported by an MCS and has bleeding, according to *Policy 6.1.C.vii* below.
- 78 • Is supported by an MCS and has aortic insufficiency, according to *Policy 6.1.C.viii* below.
- 79 • Is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7
 80 days, according to *Policy 6.1.C.ix* below.
- 81 • Is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular
 82 assist device (LVAD) after 14 days, according to *Policy 6.1.C.x* below.
- 83 • Is supported by a percutaneous endovascular mechanical circulatory support device after 14
 84 days, according to *Policy 6.1.C.xi* below.
- 85 • Is supported by an intra-aortic balloon pump (IABP) after 14 days, according to *Policy*
 86 *6.1.C.xii* below.
- 87 • Is supported by a MCS and has life threatening ventricular arrhythmia after 7 days,
 88 according to *Policy 6.1.C.xiii* below.

89 90 **6.1.C.iv Mechanical Circulatory Support Device (MCS) with Pump** 91 **Thrombosis**

92 A candidate's transplant program may assign a candidate to adult status 3 if the
 93 candidate is supported by an MCS, ~~and is experiencing pump thrombosis as~~
 94 evidenced by at least one of the following is admitted to the hospital that registered
 95 the candidate on the waiting list, and meets either of the following criteria:
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- 97 • ~~Visually detected thrombus in a paracorporeal ventricular assist device (VAD)~~

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- ~~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~~
 1. Suspected pump thrombosis in an implanted LVAD,
 - Must have one of the following conditions:
 1. Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease,
 2. Requiring inotropic support and presence of left-sided heart failure not explained by structural heart disease such as Aortic Insufficiency (AI) [as defined Policy 6.1.C.vii], as demonstrated by
 - Pulmonary Capillary Wedge Pressure (PCWP) greater than 15, and
 - Mean Arterial Pressure (MAP) less than 90, or
 3. Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control;
 - Must be receiving one of the following treatments in the hospital:
 1. Intravenous anticoagulation (e.g. heparin),
 2. Intravenous thrombolytics (e.g. tPA), or
 3. Intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban)
 2. Suspected pump thrombosis in a dischargeable paracorporeal device:
 1. Visually detected thrombus in a paracorporeal ventricular device (VAD), or
 2. TIA lasting less than 24 hours or RIND lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), ischemic Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease (as an example, ulcerated greater than 50% plaque); and
 3. Need for treatment intravenous anticoagulation (e.g. heparin), intravenous thrombolytics (e.g. tPA), or intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban) in the hospital

This status is valid for up to ~~1430~~ days from submission of *the Heart Status 3 Justification Form*. After the initial ~~1430~~ days, this status can be extended by the

141 transplant program every ~~14~~90 days by submission of another *Heart Status 3*
 142 *Justification Form*.

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 144 **6.1.C.v Mechanical Circulatory Support Device (MCS D) with Right Heart**
 145 **Failure**

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

- 150
 151 1. Has been treated with at least one of the following therapies for at least 14
 152 consecutive days, and requires ongoing treatment with at least *one* of the
 153 following therapies:
- 154 • Dobutamine greater than or equal to 5 mcg/kg/min
 - 155 • Dopamine greater than or equal to 4 mcg/kg/min
 - 156 • Epinephrine greater than or equal to 0.05 mcg/kg/min
 - 157 • Inhaled nitric oxide
 - 158 • Intravenous prostacyclin
 - 159 • Milrinone greater than or equal to 0.35 mcg/kg/min
- 160 2. Has, within 7 days prior to initiation of any of the therapies above, pulmonary
 161 capillary wedge pressure less than 20 mmHg and central venous pressure
 162 greater than 18 mmHg within one 24 hour period.

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 164 This status is valid for up to 14 days from submission of *the Heart Status 3*
 165 *Justification Form*. After the initial 14 days, this status can be extended by the
 166 transplant program every ~~14~~90 days by submission of another *Heart Status 3*
 167 *Justification Form*.

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 169 **6.1.C.vi Mechanical Circulatory Support Device (MCS D) with Device**
 170 **Infection**

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

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Table 6-1: Evidence of Device Infection

If the candidate has evidence of:	Then this status is valid for up to:
<p>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, <u>requiring IV antibiotics and either:</u></p> <ul style="list-style-type: none"> • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the driveline exit site and the device 	<p>14 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p>Debridement of the driveline with positive cultures from sites between the driveline exit site and the device <u>requiring IV antibiotics</u></p>	<p>14 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p><u>Recurrent debridement</u></p>	<p><u>90 days from submission of the <i>Heart Status 3 Justification Form</i>.</u></p>
<p>Positive culture of material from the pump pocket of an implanted device</p>	<p>90 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p>Bacteremia treated with antibiotics</p>	<p>42 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>
<p>Recurrent bacteremia that recurs from the same organism within four weeks of completing antibiotic treatment to which the bacteria is susceptible</p>	<p>-90 days from submission of <i>the Heart Status 3 Justification Form</i>.</p>

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After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form* if the candidate continues to meet the criteria and has experienced the condition within the timeframe established in Table 6-1: Evidence of Device Infection or currently requires IV antibiotics.

6.1.C.xiii Mechanical Circulatory Support Device (MCS) with Life Threatening Ventricular Arrhythmia After 7 Days

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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 placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias or receiving continuous intravenous antiarrhythmic therapy, and has already been assigned to

192 status 1 according to Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD)
193 with Life Threatening Ventricular Arrhythmia for 7 days.

194
195 This status is valid for up to 7 days from submission of the Heart Status 3
196 Justification Form. After the initial 7 days, this status can be extended by the
197 transplant program every 7 days by submission of another Heart Status 3
198 Justification Form.

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200 #