

Retrospective Public Comment for Emergency Policy

Modify Heart Policy to Address Patient Safety Following Device Recall

OPTN Heart Transplantation Committee

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Modify Heart Policy to Address Patient Safety Following Device Recall

<i>Affected Policy:</i>	<i>6.4: Adult and Pediatric Status Exceptions</i>
<i>Sponsoring Committee:</i>	<i>Heart Transplantation</i>
<i>Executive Committee Date:</i>	<i>July 11, 2022</i>
<i>Public Comment Period:</i>	<i>August 3, 2022 – September 28, 2022</i>

Executive Summary

Mechanical circulatory support devices (MCS) have long been an essential treatment for severe heart failure.¹ MCSs are commonly used for bridge-to-transplant therapy, as well as temporary bridge-to-recovery therapy and a permanent solution to severe heart failure. Despite the increased reliance on MCSs as heart failure therapies, Organ Procurement and Transplantation Network (OPTN) policy does not specifically address how to ensure patient safety if, and when, an implanted heart device is subject to a recall by the United States Food and Drug Administration (FDA). Beginning in June 2021 and continuing through June 2022, the FDA issued multiple recall notices related to a specific type of MCS. In a February 2022 letter to the OPTN Heart Transplantation Committee (Committee), the device manufacturer stated that the device's delay in restarting or failing to restart was linked to a total of ten deaths worldwide.

After receiving the letter and as the FDA recalls continued, the Committee unanimously supported an emergency policy action to address patient safety concerns in the U.S. associated with the MCS. The OPTN Executive Committee, acting on behalf of the OPTN Board of Directors,² approved the Committee's policy change on July 11, 2022 as allowed for in the emergency actions pathway established in OPTN Bylaw 11.7. The emergency policy allows a transplant program to proactively assign a heart candidate with a FDA recalled heart device to a more urgent and appropriate heart status. Transplant programs can now request an exception for an adult heart status 1, 2, or 3 in the event that a transplant candidate's implanted MCS is subject to a recall by the FDA, even if the candidate is not hospitalized at the time.

The policy change was implemented on July 14, 2022 and will expire on July 13, 2023 without further action. This emergency policy is being submitted for retrospective public comment in accordance with the OPTN Final Rule and OPTN Bylaw 11.7. After public comment, the Committee will prepare policy for permanent consideration by the OPTN Board of Directors in December 2022.

¹ Sen, Ayan, Joel S. Larson, Kianoush B. Kashani, Stacy L. Libricz, Bhavesh M. Patel, Pramod K. Guru, Cory M. Alwardt, Octavio Pajaro, and J. Christopher Farmer. "Mechanical Circulatory Assist Devices: a Primer for Critical Care and Emergency Physicians." *Critical Care (London, England)* 20, no. 1 (2016): 153–153. <https://doi.org/10.1186/s13054-016-1328-z>. Stehlik, Josef, and James K Kirklin. "The Long and Winding Road to an Effective Left Ventricular Assist Device: The Demise of Medtronic's HVAD." *Circulation (New York, N.Y.)* 144, no. 7 (2021): 509–11. <https://doi.org/10.1161/CIRCULATIONAHA.121.056027>.

² OPTN Bylaws, *Article IV Executive Committee*, (December 6, 2021), ("Considers any issues that require expedited action between meetings of the Board of Directors.").

Purpose

The OPTN Executive Committee's approval of this emergency policy addresses situations where an implanted MCS D has the potential for impending failure and the implanted device or one of its implanted components is under recall by the FDA. The approved emergency policy is submitted for retrospective public comment and seeks community feedback regarding the policy and contains several specific questions for consideration.

The circumstances surrounding a recent device recall underscored the magnitude of the problem which this policy addresses. On June 3, 2021, the FDA issued a letter to health care providers stating that issues had been identified with a durable left ventricular assist device (LVAD) which is one type of MCS D. The sale and distribution of the device was stopped. The issues included:

- Increased neurological adverse events and mortality associated with the internal pump implanted in the device recipient, and
- The potential for the internal pump to stop, resulting in delayed restarts or a failure to restart³

During the Heart Committee's presentation to the Executive Committee regarding the proposed policy changes, the members discussed how electrical issues involving the device's batteries, controller, and cables contributed to the restart issues. Exchanging the device's battery pack as well as the normal usage of the controller and cables were identified as factors that could increase the likelihood that the device had a delayed restart or failed to restart. Because most device recipients are not admitted to a hospital, they are responsible for maintenance of the batteries, controller, and cables. It was determined that the way the battery packs were maintained could result in damage to the overall system, including battery life, affected whether the device would experience problems. Subsequent FDA recalls have been issued for additional pieces of equipment associated with the LVAD as a system. **Table 1** identifies significant FDA actions taken related to the device since June 2021.

³ United States Food and Drug Administration, "Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers," June 3, 2021, <https://www.fda.gov/medical-devices/letters-health-care-providers/stop-new-implants-medtronic-hvad-system-letter-health-care-providers>, (accessed July 12, 2022).

Table 1: Dates and Events of a Recent Heart Device Recall⁴

Date	Event
June 3, 2021	FDA issued a letter to healthcare providers stating that the sale and distribution of the system has been stopped because of: <ul style="list-style-type: none"> • An increased risk of neurological adverse events and mortality associated with the internal pump • A potential for the internal pump to stop. If the internal pump stops, it may delay restarting or fail to restart
August 12, 2021	FDA issued a recall notice indicating the FDA classified the June 3, 2021 actions to stop the sale and distribution of the system because the product could cause serious injury or death
April 28, 2022	FDA issues a letter to healthcare providers to alert them to the possibility that patients who have the device and system and appear to present with pump thrombosis may have a weld defect in the internal pump causing the pump to malfunction
June 10, 2022	FDA issued a recall notice indicating the FDA classified the April 2022 recall related to actions to alert healthcare providers to a possibility of a weld defect in the internal pump because the product could cause serious injury or death
June 23, 2022	FDA issued a recall notice indicating the FDA classified the May 2022 recall related to a welding defect affecting internal Battery components from a single lot because the product could cause serious injury or death

Furthermore, it has been noted that the probability of the implanted pump experiencing a delayed restart or failing to restart increases with the amount of time the person is supported by the implanted device.⁵ It was the consensus of the OPTN Heart Transplantation Committee members that additional FDA recalls were likely to be issued in the future.⁶

Transplant candidates with the current recalled device are typically registered on the waiting list as adult heart status 4. They are considered clinically stable and therefore, not admitted to a hospital. As shown in **Table 2**, there were a total of 170 registrations on the heart waiting list as of June 17, 2022, where it was indicated that the device in question was implanted. Of those 101 registrations, almost 60 percent, were assigned to status 4. The recalls are associated with specific lot or model numbers which are not collected by the OPTN and therefore the data presented indicate the number of candidates who may be potentially impacted by the recalls.

Candidates who have the recalled device implanted faced two-policy related issues preventing them from prospectively being assigned to a higher medical urgency status. First, in order to meet the eligibility criteria for status 2 associated with *Policy 6.1.B.ii: Mechanical Circulatory Support Device (MCSD) with Malfunction*, a candidate must be experiencing the malfunction at the time the status assignment is requested. That is unlikely for most of those impacted. Second, because those impacted by the recall largely were not hospitalized, they were previously ineligible for status 1, 2, or 3 by exception. The emergency action changed policy to allow for exception requests at the higher statuses and thus opened an avenue for these candidates to receive higher prioritization.

⁴ United States Food and Drug Administration website, <https://www.fda.gov/medical-devices/cardiovascular-devices/medtronic-heartware-ventricular-assist-device-hvad-system>, (accessed July 8, 2022).

⁵ United States Food and Drug Administration website, <https://www.medtronic.com/content/dam/medtronic.com/global/HCP/Documents/hvad-prod-perf-update/hvad-urgent-medical-device-notice-december-2021.pdf> (accessed July 8, 2022).

⁶ Meeting Summary for July 7, 2022 meeting, OPTN Heart Transplantation Committee.

Table 2: Heart Waiting List Registrations as of June 17, 2022 Where Candidate Had a Device That Could Be Subject to FDA Recall

Adult Heart Status	Number of Registrations With a Potentially Recalled Device	Registrations With Potentially Recalled Device as Percentage of Total
1	0	0.0%
2	5	2.9%
3	22	12.9%
4	101	59.4%
5	0	0.0%
6	1	1.0%
7	41	24.1%
Total	170	100.0%

Background

The transplantation of adult hearts relies heavily on the use of MCSDs to bridge candidates to transplant. MCSDs are also used as destination therapy for many individuals with heart failure.

In December 2016, the OPTN Board of Directors approved modifications to adult heart allocation policy, in part, to “reflect the increased use of MCSD and increased prevalence of MCSD complications.”⁷ The Briefing Paper supporting the proposed changes documented that in 2007, approximately nine percent of candidates were first registered on the waiting list using MCSD-related criteria.⁸ The figure ballooned to almost 25 percent by 2015.⁹ The use of MCSDs has continued growing; from October 18, 2018 through October 17, 2019, approximately 56 percent of new registrations on the adult heart waiting list had a MCSD implanted at the time of listing.¹⁰

The policy modifications approved by the Board of Directors in 2016 represented a substantial effort to stratify candidates based on the type of MCSD support and the risks associated with specific device complications.¹¹ For example, *Policy 6.1.B.iii: Mechanical Circulatory Support Device (MCSD) with Malfunction* establishes the eligibility criteria for an adult heart candidate who is experiencing a device malfunction to be assigned to adult heart status 2. A candidate experiencing pump thrombosis with their MCSD is eligible for assignment to adult status 3 based on *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis*. Despite the growth in the use of MCSDs and the introduction of more specific eligibility criteria for their use, current heart allocation is less specific about the appropriate status assignment for a candidate whose MCSD is the subject of a FDA recall.

⁷ “Proposal to Modify the Adult Heart Allocation System,” OPTN Thoracic Organ Transplantation Committee, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf (accessed July 7, 2022).

⁸ Ibid.

⁹ Ibid.

¹⁰ OPTN Descriptive Data Request, “Two-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System,” Prepared for Heart Committee Conference Call, March 16, 2021, Table 5: Mechanical Circulatory Support Devices at Listing for Adult Heart Candidates.

¹¹ “Proposal to Modify the Adult Heart Allocation System,” December 2016.

Overview of Policy

The policy approved by the Executive Committee modifies *Policy 6.4: Adult and Pediatric Status Exceptions* by adding a pathway for transplant candidates impacted by heart device FDA recalls to pursue an exception request that does not require hospitalization as an eligibility criterion. More specifically, the policy permits a transplant program to request an exception for assignment at adult heart statuses 1, 2, or 3 for a candidate whose implanted mechanical circulatory support device, or an implanted component of the device, has been recalled by the FDA. A device recall-specific exception request does not require a candidate to be hospitalized at the transplant program where he or she is registered on the waiting list. This is a departure from current OPTN policy where the hospitalization requirement associated with eligibility for an adult status 1, 2, or 3 exception reflects the medical urgency the heart community places on those statuses.

As part of the approved policy changes, transplant physicians are responsible for determining whether the potential clinical condition of a candidate impacted by a device recall has the urgency and potential for benefit comparable to that of candidates assigned to adult heart statuses 1, 2, or 3. The Committee members considered whether candidates impacted by device recalls should automatically be eligible for status 2 by exception or status 3 by exception, rather than opening eligibility to the three highest priority statuses. As part of their deliberations, Committee members cited the lack of available evidence, such as waiting list mortality analyses, demonstrating that some impacted candidates should be prioritized on the waiting list ahead of others. The members agreed that without such supporting evidence, permitting access to the highest priority statuses aligned with the requirements of NOTA and the Final Rule to achieve the best use of donated organs and promote patient access. It also limited potential criticisms that the policy was arbitrarily designed. The members also indicated that any proposal must support a transplant program's ability to protect the safety of its patients. Therefore, the policy does not assign candidates impacted by a recall to a specific status, but rather leaves responsibility for determining the appropriate status with the patient's transplant physician.

Exception requests associated with device recalls will follow the same process for review as other exception requests. The initial request is reviewed retrospectively by adult heart regional review boards (RRB) for approval or denial. Initial exception requests approved by a RRB result in the candidate being assigned to the requested status for 14 days. Following the initial 14-day assignment, a transplant program may request an extension of a candidate's assignment. If approved, the extension provides the candidate with up to another 14 days at the statuses. There is no limit on the number of extensions a candidate may apply for (or be approved for) associated with a device recall exception.

As the Committee developed the proposal the members were deeply concerned with ensuring the new exception pathway is only available in instances where the FDA recall involves protecting patient safety from the risks of serious injury, major surgeries, or death. The Committee members pointed out that previous FDA recalls of heart devices have included components that are not surgically implanted, like battery packs. A member of the Executive Committee raised a similar question about the proposal, noting that previous emergency policies generally resulted in the changes being applied consistently to all impacted candidates; whereas, this policy did not. By developing language that specifically identifies implanted devices and implanted components, the members sought to preclude non-life-threatening events from using the exception pathway, while also making a concerted effort not to prevent the use of an exception to address an individual circumstance that could not be captured through a more detailed or narrow set of eligibility requirements. The Committee strongly believed the proposed policy achieves that goal. At the same time, the members acknowledged that educational materials were needed to provide additional details about acceptable versus unacceptable uses.

Per Policy 6.3: *Status Updates*, use of the exception request process for a device recall is no longer available to a candidate whose medical condition changes and the criteria used to justify the candidate's status is no longer accurate. As such, if the recalled device is explanted, the candidate no longer qualifies for the exception. The requirement still applies that the candidate's transplant program must update the candidate's status and report the updated information to the OPTN within 24 hours of the change in medical condition.

If a RRB denies the initial exception request or any subsequent requests to extend the approved exception, the existing heart exception appeals process is available to transplant programs to pursue another review.

NOTA and Final Rule Analysis

The Committee submitted the proposal for consideration under the authority of the National Organ Transplantation Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the Organ Procurement and Transplantation Network (OPTN) to "establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."¹² The OPTN Final Rule states that the OPTN "shall be responsible for developing...policies for the equitable allocation of cadaveric organs."¹³

The Committee submitted this proposal for the OPTN Executive Committee's consideration, acting on behalf of the OPTN Board of Directors,¹⁴ under the authority of NOTA, which requires the OPTN to "establish...medical criteria for allocating organs and provide members of the public an opportunity comment with respect to such criteria..."¹⁵ The Committee also submitted the proposal under the authority of the OPTN Final Rule, which states "[t]he OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs."¹⁶ The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."¹⁷

As approved by the Executive Committee, this emergency policy:

- **Is based on sound medical judgment**¹⁸ because it is an evidenced-based change relying on the medical experience and expertise of the Committee to better align candidates' medical urgency

¹² 42 USC §274(b)(2)(B)

¹³ 42 CFR §121.4(a)(1)

¹⁴ OPTN Bylaws, *Article IV Executive Committee*, (December 6, 2021), ("Considers any issues that require expedited action between meetings of the Board of Directors.").

¹⁵ 42 USC § 274(b)(2)(B)

¹⁶ 42 CFR § 121.4(a)(1)

¹⁷ 42 CFR § 121.8(a)

¹⁸ 42 CFR §121.8(a)(1)

based on the candidates' clinical condition if their devices failed with the medical urgency of comparable candidates,

- **Seeks to achieve the best use of donated organs¹⁹** by ensuring organs are allocated and transplanted according to medical urgency. The policy is designed to ensure that candidates with implanted devices subject to a FDA recall have the opportunity to be assigned to a heart status reflecting their medical urgency if the device fails, and therefore, have increased access to a donor organ reflective of that urgency.
- **Is designed to...promote patient access to transplantation²⁰** by giving similarly situated candidates equitable opportunities to receive an organ offer. Candidates impacted by a FDA device recall will have equitable opportunities to receive an organ offer based on their potential clinical condition, as determined by the transplant physician, if their implanted device were recalled.

This policy also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,²¹ and it is specific to an organ type, in this case hearts.²²

Although the approved policy addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- **Is designed to avoid wasting organs²³** by decreasing the number of donor hearts recovered but not transplanted.
- **Is designed to avoid futile transplants²⁴** because the proposal should not result in transplanting patients who are unlikely to have good post-transplant outcomes.
- **Promote the efficient management of organ placement²⁵** by taking into account the costs and logistics of procuring and transplanting organs
- **Is not based on the candidate's place of residence or place of listing²⁶**

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies” whenever organ allocation policies are revised.²⁷ The Committee considered whether the proposed policy changes would result in any heart population or group being treated less favorably than they would have been treated under the previous policies. The only group the Committee identified was those candidates assigned to statuses 1, 2, or 3 who might have their place on the waiting list reduced as a candidate impacted by a device recall is assigned at the same status. However, the impact of such changes is expected to be very small due to the low volume of adult heart candidates eligible to use the proposed exception pathway.

¹⁹ 42 CFR §121.8(a)(2)

²⁰ Ibid.

²¹ 42 CFR §121.8(a)(3)

²² 42 CFR §121.8(a)(4)

²³ 42 CFR §121.8(a)(5)

²⁴ Ibid.

²⁵ Ibid.

²⁶ 42 CFR §121.8(a)(8)

²⁷ 42 CFR §121.8(d)

The Executive Committee is authorized to approve emergency policies according to OPTN *Bylaw 11.7: Emergency Actions*. Under Bylaw 11.7, an emergency policy is permissible if it is required due to an emergent public health issue or *patient safety factors* (emphasis added).²⁸ The consensus of the Heart Committee members was that an emergency action was required to address a patient safety factor associated with a recalled durable LVAD.²⁹ Based on the clinical factors associated with the recalls, as well as the volume of recalls, the Committee recommended that the OPTN Executive Committee approve the proposed policy modifications as an emergency action in order for the changes to be implemented as soon as possible.³⁰

Bylaw 11.7 requires that emergency policy changes designate a future date upon which the policy will expire. The future date can be no more than 12 months beyond the policy's effective date. The emergency policy became effective on July 14, 2022, and is scheduled to expire on July 13, 2023. Following the retrospective public comment period, the Heart Committee will prepare the policy for permanent consideration by the OPTN Board of Directors in December 2022.

In addition, the emergency policy must be distributed for public comment no more than six months after approval. The policy will be distributed for public comment on August 3, 2022.

Implementation Considerations

Member and OPTN Operations

Transplant hospitals and the OPTN took actions to implement the proposal. The changes were not expected to affect the operations of the organ procurement organizations (OPO) or histocompatibility laboratories.

Operations affecting Transplant Hospitals

Transplant program staff need to be familiar with the circumstances under which an exception is permissible and the clinical information that should be provided in the narrative describing a candidate's condition. Transplant programs are expected to have educated staff regarding the availability of the exception request pathway associated with a device recall.

When using the exception pathway created for device recalls, transplant programs must document any materials or information associated with the recall in the candidate's medical record. The documentation must include the circumstances that support using the emergency policy.

Operations affecting the OPTN

The OPTN communicated the emergency policy action to all OPTN members through the use of both a pre-implementation policy notice issued on July 11, 2022 and a policy notice on July 14, 2022, and other appropriate communications on the OPTN website. In addition, OPTN members received targeted communications about the policy change as well as the implementation of the changes. Educational materials were made available on July 14, 2022.

The action required implementation in the OPTN Computer System. OPTN Waiting List documentation was revised to accommodate the creation of an exception associated with a "device recall." To utilize

²⁸ OPTN Bylaw 11.7, *Emergency Actions* (December 6, 2021).

²⁹ Meeting Summary for July 7, 2022 meeting, OPTN Heart Transplantation Committee.

³⁰ Ibid.

the exception, a transplant program follows the existing process to indicate the status assignment request is associated with an exception. The program is then prompted to indicate whether the exception request is associated with a device recall. An affirmative response permits the request to be submitted for review even if the form indicates that the candidate is not currently admitted to the hospital. A description of the proposed new data elements can be found in **Appendix A: Proposed Data Elements and Definitions**.

Potential Impact on Select Patient Populations

The policy has the potential to impact select patient populations. In particular, as candidates with FDA-recalled devices meeting eligibility criteria established in policy are assigned to higher priority statuses, candidates already assigned to those statuses may experience slightly reduced access to donor organ offers. Because only a small volume of adult heart candidates is expected to be eligible to utilize the exception pathway, the impact on candidates already assigned to those statuses is expected to also be small.

Projected Fiscal Impact

This policy is expected to have a minimal fiscal impact on the OPTN and transplant hospitals, while histocompatibility laboratories and organ procurement organizations are not expected to experience a fiscal impact.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is no expected fiscal impact for organ procurement organizations.

Projected Impact on Transplant Hospitals

The policy is not expected to have a substantial fiscal impact on transplant hospitals, in part due to the small number of patients expected to be eligible for the proposed exception pathway. Transplant hospital staff need to be familiar with the circumstances by which an exception request related to a FDA device recall can be submitted, as well as the type of information that should be included in the clinical narrative supporting the request. Completion of an initial exception request and potential subsequent requests to extend a patient's assignment by exception could likely be part of standard hospital operations.

Some transplant hospitals may need to make changes to their electronic data reporting systems to account for the new data element being collected.

Projected Impact on the OPTN

This policy had a fiscal impact on the OPTN as a result of the IT changes in the OPTN Computer System. The proposal resulted in implementation of data collection changes in OPTN Waiting List and communications to members about those changes. The policy will also result in additional monitoring in the future. The Committee is seeking feedback from the community regarding several questions and considerations about the policy. If the community's feedback were to lead to changes in the approved policy, then additional fiscal impacts could result.

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.”³¹

This policy 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 the OPTN Computer System 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.”³² This policy will be formally evaluated at approximately 3 months, 6 months, and 1 year 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, where appropriate. Timeline is subject to change based on the results. Data will be presented in tabular and graphical form as appropriate.

The following metrics and any others subsequently requested by the Committee, will be evaluated:

- The number and percent of all registrations that submitted a ‘device recall exception’
- The number and percent of registrations ever waiting by medical urgency status and criteria within medical urgency status (including ‘device recall exception’)
- The number and percent of waitlist additions by medical urgency status and criteria within medical urgency status (including ‘device recall exception’)
- The number and percent of waitlist additions by medical urgency status and criteria within medical urgency status (including ‘device recall exception’) and by month
- The number and percent of transplants by medical urgency status and criteria within medical urgency status (including ‘device recall exception’)

Conclusion

The emergency policy developed by the OPTN Heart Transplantation Committee and approved by the OPTN Executive Committee addresses an emergent need to protect the patient safety of certain adult heart transplant candidates who are impacted by FDA-issued recalls of their implanted devices.

³¹ 42 CFR §121.8(a)(7)

³² 42 CFR §121.8(a)(6)

The changes permit a transplant program to request an exception for an adult heart status 1, 2, or 3 in the event that a transplant candidate's implanted MCS, or a component within the MCS, is subject to a recall by the FDA, even if the candidate is not hospitalized at the time. The candidate's transplant physician must determine that the MCS is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device. The Committee's intention is for the new pathway to protect the safety of those whose devices have been recalled, but remain clinically stable.

Considerations for Community

The Committee requests feedback on the following questions:

- Should the approved emergency policy changes be considered for permanent policy by the OPTN Board of Directors?
- What, if any, data analyses, peer-reviewed literature, or evidence-based medical judgments, provide evidence demonstrating that a patient with FDA-recalled heart device should be assigned to adult heart status 2 or adult heart status 3 by policy criteria, rather than a candidate's transplant physician determining whether assignment to status 1, 2, or 3 by exception is appropriate?
- Is 14 days the appropriate amount of time for a candidate impacted by a FDA-recalled device to be initially assigned to status 1, 2, or 3 under the approved policy? Why or why not?
 - Is 14 days the appropriate amount of time for an extension of the assignment by exception? Why or why not?
- In addition to the Member Compliance and Policy Evaluation actions identified in the proposal, what other actions can be taken to ensure the new exception pathway is only used for appropriate purposes as intended by the Heart Committee?
- Are there any types of implanted devices that could be subject to a FDA device recall that should not qualify under the policy modifications? Describe why.
- Are there any types of devices that are not implanted that should be permitted to qualify under the policy modifications? Describe why.
- Are the proposed data element and the associated data definition clear and understandable?
- Are the acceptable forms of documentation regarding the recall of the device identified in the proposal widely available?

Policy Language

Policy language underlined (example) was emergently adopted by the Executive Committee. The proposed underlined (example) language is now subject to retrospective public comment. Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **6.4 Adult and Pediatric Status Exceptions**

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

3

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Table 6-3: Exception Qualification and Periods

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

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
	benefit comparable to that of other candidates at the requested status			requests retrospectively
<u>Adult status 1, 2, or 3</u>	<p>1. <u>Candidate's implanted mechanical circulatory support device, or an implanted component within, has a U.S. Food and Drug Administration recall that the transplant physician determines is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component, and</u></p> <p>2. <u>Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</u></p>	<u>RRBs retrospectively review requests for exceptions associated with a heart device recall</u>	<u>14 days</u>	<ul style="list-style-type: none"> • <u>Require RRB approval for each successive 14 day period</u> • <u>RRB will review and decide extension requests retrospectively</u>
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	<ul style="list-style-type: none"> • Require RRB approval for each successive 90 day period • RRB will review and decide extension requests retrospectively
Pediatric status 1A	<ul style="list-style-type: none"> • Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and • Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for 	The national heart review board (NHRB) retrospectively review requests for Status 1A-exceptions	14 days	<ul style="list-style-type: none"> • Require the NHRB approval for each successive 14 day period • The NHRB will review and decide extension

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
	benefit comparable to that of other candidates at the requested status			requests retrospectively • If no extension request is submitted, the candidate will be assigned pediatric status 1B
Pediatric status 1B	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	The NHRB retrospectively review requests for Status 1B exceptions	Indefinite	• Not required as long as candidate's medical condition remains the same

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Appendix A: Proposed Data Elements and Definitions

The Committee determined that the following new data element was needed if the exception request is associated with a heart device recall issued by the United States Food and Drug Administration. This data element was implemented on July 14, 2022.

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Data Element	Current Definition	Proposed Definition
This exception request is specifically related to a device recall	This is a new data element	Candidate does not meet any of the criteria above but has an urgency and potential for benefit comparable to that of other candidates at the status and is either admitted to the transplant hospital that registered the candidate on the waiting list, or candidate’s implanted mechanical circulatory support device, or an implanted component within, has a U.S. Food and Drug Administration recall that the transplant physician determines is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component.

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