

At-a-Glance

- **Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNetSM a Change in Criterion or Status within Twenty-Four Hours of that Change**
- **Affected Policies: 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status)**
- **Thoracic Organ Transplantation Committee**

The OPTN Contractor’s policy evaluation plan requires that heart transplant programs record in UNetSM changes to a heart transplant candidate’s status or criterion within 24 hours, but this requirement is not written in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The two policies state that the OPTN Contractor will notify “a responsible member of the transplant team” prior to downgrading a candidate’s Status, but the OPTN Contractor does not notify such personnel in addition to displaying the candidate’s status in UNetSM. The proposed modification includes the 24-hour requirement, removes of the notification clause, and includes edits for plain language. For consistency, the modifications also include language about potential referral of pediatric heart status exception case decisions to the Thoracic Organ Transplantation Committee.

- **Affected groups**
 - Transplant Administrators
 - Transplant Data Coordinators
 - Transplant Physicians
 - Transplant Surgeons
 - Public Relations Staff
 - Public Education Staff
 - Transplant Program Directors
 - General Public
- **Number of Potential Candidates Affected**

The proposed modification may affect adult and pediatric heart transplant candidates.
- **Compliance with OPTN Strategic Goals and Final Rule**

The proposed policy modification addresses the “best use” program and strategic plan goal of the Health and Human Services and the OPTN, respectively. The following constructs in the OPTN Final Rule also support this proposal:

 - §121.8 Allocation of organs.
 - (a) Policy development. [...]
 - (2) Shall seek to achieve the best use of donated organs; [...]
 - (6) Shall be reviewed periodically and revised as appropriate; [...]

Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNetSM a Change in Criterion or Status within Twenty-Four Hours of that Change

Affected Policies: 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status)

Thoracic Organ Transplantation Committee

Summary and Goals of the Proposal:

The OPTN Contractor's policy evaluation plan¹ requires that heart transplant programs record in UNetSM changes to a heart transplant candidate's status or criterion within 24 hours, but this requirement is not written in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The two policies state that the OPTN Contractor will notify "a responsible member of the transplant team" prior to downgrading a candidate's Status, but the OPTN Contractor does not notify such personnel in addition to displaying the candidate's status in UNetSM. (Clinicians may view a candidate's status at any time in UNetSM.) The proposed modifications include the 24-hour requirement, removal of the notification clause, and edits for plain language. For consistency, the modifications also include language about potential referral of pediatric heart status exception case decisions to the Thoracic Organ Transplantation Committee (Committee).

Background and Significance of the Proposal:

On March 10, 2008, the OPTN/UNOS Membership and Professional Standards Committee (MPSC) posed the following questions to the Committee:

Issue 1. After a candidate qualifies for Status 1A, must the candidate continue to meet the qualification criterion each day for Status 1A in order to retain that status? Or, after a candidate qualifies for Status 1A, does the candidate remain as Status 1A for the maximum number of days the qualification may remain valid as defined in policy, even if the candidate's medical condition changes?

Issue 2. After a patient qualifies for Status 1A, and the patient's status changes such that he/she no longer qualifies for Status 1A, or qualifies for Status 1A under a different qualification criterion, what is required of the transplant center regarding documenting the change in medical condition in UNetSM?

While the Committee provided the following response to the MPSC, it did not modify policies 3.7.3 and 3.7.4 at that time:

- The heart status policy language, especially with the use of the word "continuous," is clear. If a given status criterion isn't met, then the center has to change the candidate's status, as appropriate. However, given that there are questions about this policy language, the Committee will further clarify the policy language to ensure understanding in the thoracic policy rewrite effort.

¹ http://optn.transplant.hrsa.gov/content/policiesAndBylaws/evaluation_plan.asp

- Regarding issue #1 above, the candidate should be considered a heart Status 1A only if the requirements outlined in policy are met.
- Regarding issue #2 above, the Committee expects the transplant center to update a heart candidate's heart status within 24 hours of the change in medical condition.

The decision to codify the 24-hour requirement occurred on March 22, 2011. The Committee considered time periods less than 24 hours for reporting a candidate's accurate criterion or Status to the OPTN Contractor. During a 24-hour time period, changes in a candidate's medical urgency status could occur, possibly resulting in the candidate receiving a heart offer while listed at a Status that may not be current. However, the 24-hour time period is what the Department of Evaluation and Quality currently uses to evaluate the accuracy of a medical urgency status listing; so, this time period is already in practice within the heart transplant community. The Committee voted in favor of the 24-hour time frame within which a transplant program must notify the OPTN Contractor – through UNetSM – of any change in an adult or pediatric heart candidate's criterion or Status: 20-supported; 0-opposed; and, 0-abstained. On June 13, 2011, the Committee voted in favor of submitting this policy modification for public comment: 15-supported; 0-opposed; and, 0-abstained.

In August, 2011, the Committee voted in favor of the proposed policy changes: 23-supported; 0-opposed; and, 1-abstained. The Pediatric Organ Transplantation Committee voted in favor of the proposed policy changes: 20-supported; 0-opposed; and, 0-abstained.

Supporting Evidence:

The proposed modifications state the Committee's intent that transplant programs must report criterion or status changes to the OPTN Contractor, via UNetSM, within 24 hours of the change. The OPTN Contractor does not actively notify transplant programs about candidate status downgrades; rather, the OPTN Contractor, via UNetSM, informs transplant programs about candidate medical urgency status, days remaining at that status, and displays other candidate-specific information.

The Committee may review heart regional review board decisions on adult and pediatric status exception requests. The Committee has the authority to forward adult and pediatric cases to the MPSC for review.

If UNetSM changes a candidate's Status to 1B automatically due to a lack of re-certification of a Status 1A criterion, the candidate's attending physician must provide the information on the blank Status 1B form generated by UNetSM. However, if the candidate's medical condition does not qualify her or him for Status 1A or 1B listing, then the physician must list the candidate as Status 2 or 7. The physician may opt to list the candidate as Status 1A or 1B by exception, but this listing requires approval from the regional review board.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

The proposed modification may affect adult and pediatric heart transplant candidates. (Depending on

how transplant programs manage their waiting list population, and depending on the geographic location and medical urgency status of potential recipients on the match run, the proposed policy may not affect heart transplant candidates at all.) Changes made to these candidates' statuses may affect their prioritization on a match run.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed policy modification addresses the “best use” program and strategic plan goal of the Health and Human Services and the OPTN, respectively. Accurately listed candidates result in deceased donor heart offers made to the most medically suitable potential recipients. Accurate data collection benefits the development of a future heart allocation score or revising the existing heart medical urgency status system. Without knowing when a candidate’s criterion or status no longer applies to her or him results in the OPTN not being able to accurately assess waiting list mortality associated with that criterion or status. This same rationale is supported also by the following constructs in the OPTN Final Rule:

- §121.8 Allocation of organs.
- (a) Policy development. [...]
- (2) Shall seek to achieve the best use of donated organs; [...]
- (6) Shall be reviewed periodically and revised as appropriate; [...]

Plan for Evaluating the Proposal:

Through site audit data, the Committee will determine the compliance rate for the proposed policy.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Since this proposal will not require programming in UNetSM, the policy will be in effect 60 days after its approval by the OPTN/UNOS Board of Directors.

Communication and Education Plan:

Communication and Education Activity			
Type of Communication	Audience	Deliver Method	Timeframe
Policy Notice	Transplant administrators Transplant data coordinators Transplant physicians Transplant surgeons Transplant program directors Heart candidates Compliance officers General public	E-mail	30 days after the Board of Directors approves the policy

Monitoring and Evaluation by the Department of Evaluation and Quality (DEQ):

Transplant centers are expected to adjust a candidate's status if the medical criterion for listing changes within 24 hours. Through on-site reviews, DEQ staff verifies candidate status listings as submitted in UNetSM and on Status Justification Forms with the actual medical record documentation.

Proposed Policy Modification:

3.7.3 Adult Candidate Status.— Each candidate awaiting heart transplantation is assigned ~~receives~~ a status code ~~which corresponds~~ corresponding to ~~how medically urgent it is that the candidate's medical urgency receive a~~ for transplant. ~~Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows~~ A heart transplant candidate at least 18 years of age at the time of listing receives a status code as follows:

Status	Definition
<u>Status 1A</u>	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for <u>a</u> 1A(b) candidates) and has at least one of the following devices or therapies in place:

- (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
 - (i) left and/or right ventricular assist device implanted
Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
 - (ii) total artificial heart;
 - (iii) intra-aortic balloon pump; or
 - (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.

- (b) Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an “other” complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

- (c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.
- (d) Continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

Status 1A by-Exception

A candidate who does not meet ~~criteria~~criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify~~and justification~~ to the applicable Regional Review Board ~~that why~~ the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of~~as other candidates in Status 1A~~this status as defined above~~. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A~~the status criteria~~. The justification must be reviewed and approved by the Regional Review Board. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. ~~A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status.~~

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A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing ~~under this criterion~~ by exception requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as

Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees~~ to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1A Justification Form

A completed Heart Status 1A Justification Form must be submitted to ~~in~~ UNetSM in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B ~~unless the attending physician recertifies the candidate's qualification for a Status 1A criterion. Note: This~~ The automatic downgrade will not require submission of a Status 1B Justification Form. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B

A candidate listed as Status 1B has at least one of the following devices or therapies in place:

- (aa) left and/or right ventricular assist device implanted; or
- (bb) continuous infusion of intravenous inotropes.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

Status 1B- by Exception

A candidate who does not meet the criteria for Status 1B may nevertheless be ~~assigned to such status~~ listed as Status 1B upon application by his or her transplant physician. The transplant physician must and justification justify to the applicable Regional Review Board ~~that why~~ the candidate is considered, using ~~accepted~~ acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of as other Status 1B candidates in this status as defined above.~~ The justification must include a rationale for incorporating the exceptional case as part of ~~Status 1B~~ the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees~~ to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form

A completed Heart Status 1B Justification Form must be submitted to UNetSM in order to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNetSM within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

3.7.4 Pediatric Candidate Status. Each candidate awaiting heart transplantation is assigned receives a status code which corresponds to how medically urgent it is that the candidate's medical urgency for receive a transplant. Medical urgency is assigned to a heart transplant candidate who is less than 18 years of age at the time of listing as follows: Pediatric heart transplant candidates who have not received a heart transplant remain on the Waiting List at the time of before their 18th birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in on Policy 3.7.4. A heart transplant candidate who is less than 18 years of age at the time of listing receives a status code as follows:

Status	Definition
<u>Status 1A</u>	A candidate listed as Status 1A meets at least one of the following criteria: (a) Requires assistance with a ventilator; (b) Requires assistance with a mechanical assist device (e.g., ECMO); (c) Requires assistance with a balloon pump; (d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

- (e) ~~Requires infusion of high dose (e.g., dobutamine > / = 7.5 mcg/kg/min or milrinone > / = .50 mcg/kg/min) or multiple inotropes (e.g., addition of dopamine at > / = 5 mcg/kg/min) (The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.); or,~~
- (f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

Submission of Status 1A Justification Form

~~For all pediatric candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received on UNetSM in order to list a candidate As as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. Candidates who are listed as Status 1A will automatically revert back to Status 1B after 14 days unless these candidates are re-listed on UNetSM as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above~~

A completed Heart Status 1A Justification Form must be submitted in UNetSM in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B

A candidate listed as Status 1B meets at least one of the following

criteria:

- (a) Requires infusion of low dose single inotropes (~~e.g., dobutamine or dopamine < / > 7.5 mcg/kg/min~~)(The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);
- (b) Less than six months old and does not meet the criteria for Status 1A; or
- (c) Growth failure *i.e.*, ~~±~~less than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5th percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. –Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate’s growth at two different times, second, calculating the candidate’s growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.*, (candidate’s growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

Status 1B by Exception

A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committees. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

~~For all pediatric candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNetSM in order to list a candidate as Status 1B. A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application~~

~~by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~

Submission of Status 1B Justification Form

A completed Heart Status 1B Justification Form must be submitted in UNetSM to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNetSM within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~