

## *At-a-Glance*

- **Proposal to Clarify Requirements for Waiting Time Modification Requests**
- **Affected/Proposed Policy: Policy 3.2.1.8 (Waiting Time Modification)**
- **Kidney Transplantation Committee**

Current OPTN policies regarding submission of waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee believes that it will receive fewer submissions of incomplete requests and be able to act on approved requests more quickly.

- **Affected Groups**

Transplant Administrators  
Transplant Data Coordinators  
Transplant Physicians/Surgeons  
Transplant Social Workers  
Organ Candidates

- **Number of Potential Candidates Affected**

The Kidney Transplantation Committee reviews approximately 25 requests for waiting time modifications annually.

- **Compliance with OPTN Strategic Goals and Final Rule**

This proposal is intended only to clarify existing policy language and the proposed language changes are not likely to substantially affect the Program Goals, Strategic Plan or Adherence to the OPTN Final Rule.

## **Proposal to Clarify Requirements for Waiting Time Modification Requests**

**Affected/Proposed Policy: Policy 3.2.1.8 (Waiting Time Modification)**

### **Kidney Transplantation Committee**

#### **Summary and Goals of the Proposal:**

Current OPTN policies regarding submission of waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee believes that it will receive fewer submissions of incomplete requests and be able to act on approved requests more quickly.

#### **Background and Significance of the Proposal:**

Organ allocation often includes priority based on the length of time since a candidate was listed for transplant while meeting defined clinical criteria (e.g., for kidney transplantation candidates, the requirements are for dialysis or a glomerular filtration rate (GFR)  $\leq 20$ ml/min). In rare situations, a candidate's listing may be delayed due to miscommunications or errors at the transplant center. In these cases, transplant programs may request a review of the case by an organ-specific committee and possible modification of the candidate's waiting time.

Current OPTN/UNOS Policy 3.2.1.8 describes the process for submitting a waiting time modification request. Unfortunately, the policy language is not user-friendly and often results in confusion or submission of incomplete documentation. Until complete documentation is received, the review process by the organ-specific Committees cannot take place. Delays in the review process adversely affect candidates and require additional resources from transplant centers and the OPTN Contractor.

These proposed changes do not alter the requirements or the process for submitting a waiting time modification request. These changes only clarify the requirements and process so that review of requests may take place more efficiently. The proposed language more clearly states which requests may be submitted for an expedited review, which committees or subcommittees review requests, and the process by which reviewers consider requests.

The Kidney Transplantation Committee reviewed these issues in July 2011 and voted on the following resolution:

**\*\*Resolved, that Policy 3.2.1.8 (Waiting Time Modification) be clarified and circulated for public comment.**

Committee vote: 14 in favor, 0 opposed, 0 abstentions

**Supporting Evidence and/or Modeling:**

Between July 1 2010 and June 30, 2011, the OPTN Contractor received 23 requests for waiting time modifications for kidney transplantation candidates. Only half of the requests for waiting time modification received by the OPTN Contractor in 2010 were received complete. The average length of time from receipt of the request until a decision was rendered by the Committee was 16.7 weeks.

**Expected Impact on Living Donors or Living Donation:**

This proposal is not expected to have any impact on Living Donors or Living Donation.

**Expected Impact on Specific Patient Populations**

This proposal is not expected to have any measurable disproportionate impact on specific patient populations.

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

This proposal is intended only to clarify existing policy language and the proposed language changes are not likely to substantially affect the Program Goals, Strategic Plan or Adherence to the OPTN Final Rule.

**Plan for Evaluating the Proposal:**

The Kidney Transplantation Committee will continue to monitor the following metrics regarding waiting time modification requests:

- Total number of requests received,
- Number of requests received with incomplete or missing documentation, and
- Length of time from receipt of request until a Committee decision is rendered.

The Committee hypothesizes that the number of incomplete requests will decline with the clarification of these policies and therefore the length of time required to review the requests will also decline.

**Additional Data Collection:**

This proposal requires no additional data collection.

**Expected Implementation Plan:**

The proposed policy language only clarifies the requirements and process for waiting time modification requests. No changes in the process or requirements for submitting a waiting time modification request are proposed. Transplant center staff who are responsible for submitting requests for waiting time modifications will need to be aware of the new policy language if/when it is approved by the Board of Directors.

## **Communication and Education Plan:**

Members will be notified of any changes to this policy through the Policy Notice which is released 30 days following an OPTN/UNOS Board of Directors meeting. A link to the Policy Notice is provided in the OPTN Member eNewsletter.

## **Monitoring and Evaluation:**

There are no changes proposed to the way that compliance with this policy will be monitored. The appropriate organ-specific committee(s) will continue to review requests for waiting time modification. The process of submitting the requests through the Organ Center will not change.

To evaluate the effectiveness of this policy, UNOS staff will assess the time from submission to Committee decision rendered for submitted requests.

## **Policy or Bylaw Proposal:**

Proposed new language is underlined below and language that is proposed for removal is ~~stricken through~~.

### **3.2.1.8 Waiting Time Modification**

#### **3.2.1.8.1 Permissible Modifications**

Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in modifying, removing, or renewing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate is waiting for a heart, liver, or lung, needs a second organ, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below.

#### **3.2.1.8.2 Application**

To apply for a waiting time modification, a candidate's Transplant Program must submit an application to the OPTN Contractor with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 *et seq.*).

3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate’s physician or surgeon.

**3.2.1.8.3 Expedited Modifications of Waiting Time**

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

1. Upon receipt of a complete application, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

**3.2.1.8.4 Modifications of Waiting Time**

All other applications for waiting time modifications must use the following process:

1. Upon receipt of a complete application and approval or explanation of disagreements from all applicable Transplant Programs within the local unit where the candidate is registered, the OPTN Contractor will forward the application, without person-identified data, as follows:

<u>If the candidate requests a modification on the following organ waiting list:</u>	<u>Then the application will be reviewed by the:</u>
<u>Kidney</u>	<u>Kidney Waiting Time Modifications Subcommittee</u>
<u>Liver</u>	<u>A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee</u>
<u>Thoracic</u>	<u>A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee</u>
<u>Pancreas</u>	<u>Pancreas Waiting Time Modifications Subcommittee</u>
<u>Intestine</u>	<u>A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee</u>

**Review of Waiting List Modification Applications**

2. The reviewer will determine if it is appropriate to modify the candidate’s waiting time as requested in the application and notify the OPTN Contractor of the decision.
3. Upon notice, the OPTN Contractor will implement the waiting time modification.
4. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.
5. The Committee will report the modification, without person-identified data, to the Board of Directors.

~~**3.2.1.8 Waiting Time Modification.** Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:~~

- ~~i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.~~
- ~~ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.~~

~~Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time.~~

~~All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting)<sub>2</sub> or Policy 3.5.12.1 (Time of Waiting)<sub>2</sub> or Policy 3.8.4.3 (Waiting time) as of the listing date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney Transplantation Committee (for kidney and kidney/pancreas candidates) or Pancreas Transplantation Committee (for kidney/pancreas and pancreas candidates), or, in the case of pediatric (i.e., less than 18 years old) kidney candidates, with approval from the Chair of the Kidney & Pancreas Transplantation Committee to proceed to a subcommittee of the full Committee followed by consideration and unanimous approval by this subcommittee. Pediatric candidate cases addressed by a subcommittee of the Kidney & Pancreas Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney, kidney pancreas, and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the Kidney Transplantation Committee & Pancreas Transplantation Committee or subcommittee in the case of pediatric candidates and Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

~~**3.2.1.8.1 Waiting Time Modification for Urgent Status Candidates.** Adjustments will be permitted to the waiting time of Status 1 liver transplant candidates, Status 1A heart transplant candidates, and Priority 1 pediatric lung candidates registered on the Waiting List if an error or miscommunication occurred in listing, modification, or accidental removal of the candidate, or in renewing the candidate's~~

status. Supporting documentation must be submitted, including a written request from the physician/surgeon in charge of the candidate's care explaining the circumstance along with the appropriate status justification form and Wait Time Modification Form. Upon receipt of completed documentation, the requested modification will be made. Each case will be reported retrospectively to the appropriate regional review board for consideration.

**3.2.107 Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises.** Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.