

At-a-Glance

Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity

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- **Affected/Proposed Bylaw:** Appendix D, Section D.9 (Review of Transplant Program Functional Activity) and Appendix K, Section 1 (Transplant Program Inactivity)

- **Membership and Professional Standards Committee (MPSC)**

- The purpose of this proposal is to better define the notification requirements for periods of functional inactivity. Currently, the Bylaws do not clearly outline the actions a Member must take when it becomes functionally inactive. This Bylaw proposal clarifies the current notification requirements for functional inactivity by including specific requirements for notification of functional inactivity, including waiting list inactivation in UNetsm. These modifications also specify what a member must do in terms of notifying patients when a program voluntarily ceases performing a specific type of transplant.

- **Affected Groups**
 - Transplant Program Directors
 - Transplant Administrators
 - Transplant Physicians/Surgeons
 - Transplant Data Coordinators
 - Organ Recipients
 - Organ Candidates
 - Living Donors

- **Number of Potential Candidates Affected**

Functional inactivity affects both potential candidates and candidates. During 2011, approximately 154,000 candidates were registered on a waiting list for at least one day.

Over the course of 2011, 12 transplant programs met notification thresholds for an inactive waiting list, which affected approximately 1,000 candidates.

Additionally, four programs ceased performing either age-specific or donor-specific transplants during 2011, which affected approximately 2,900 candidates.

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

This proposal addresses the strategic plan goal of promoting the efficient management of the OPTN. This proposal clarifies existing bylaw language regarding functional inactivity and the MPSC's review of transplant program performance. Member responsibilities and expectations are clearly defined in the proposal and will result in improved interpretation of and compliance with Bylaw requirements.

- **Specific Requests for Comment**

Please do not limit your response to the questions outlined below.

For Program Component Cessation:

- This proposal uses the phrase 'affected patients' instead of listing which patients must be notified (e.g. Should adult patients be notified of pediatric cessation; should candidates waiting for a living donor and potential living donors be notified of deceased component cessation). Is this language clear enough for members to understand which patients must be notified?
- Should adult candidates be notified of the cessation of a pediatric component of a transplant program? Similarly, should pediatric patients be notified of the cessation of an adult component of a transplant program?
- Should transplant recipients be notified of the cessation of living donor, deceased donor, or age-specific transplantation program components? Similarly, should post-donation living donors be notified of the cessation of living donor, deceased donor, or age-specific transplantation program components?
- Should there be different timelines for patient notification for living versus deceased donor program components?

Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity

Affected/Proposed Policy: Appendix D, Section D.9 (Review of Transplant Program Functional Activity) and Appendix K, Section 1 (Transplant Program Inactivity)

Membership and Professional Standards Committee (MPSC)

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The purpose of this proposal is to better define the notification requirements for periods of functional inactivity. Currently, the Bylaws do not clearly outline the actions a Member must take when it becomes functionally inactive. This Bylaw proposal clarifies the current notification requirements for functional inactivity by including specific requirements for notification of functional inactivity, including waiting list inactivation in UNetsm. These modifications also specify what a member must do in terms of notifying patients when a program voluntarily ceases performing a specific type of transplant.

Background and Significance of the Proposal:

The Bylaws currently define functional inactivity as:

1. The inability to serve potential candidates, candidates, or recipients for a period of 15 or more consecutive days.
2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.
3. The failure to perform a transplant during the periods defined in the table below:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

The MPSC currently monitors functional inactivity, including periods of wait list inactivation. The purpose of the original Bylaw was to ensure that candidates would be better informed of periods when organ offers would not be made to the transplant program on behalf of the candidates. As the MPSC has continued to monitor these programs, there have been questions from both the transplant programs and MPSC members regarding specific content requirements in the patient notifications and the timing of these notifications.

The OPTN currently does not have separate approval statuses for a subsection or component of programs (e.g. pediatric and adult or living donor and deceased). Since programs are approved to perform organ-specific transplants, regardless of the patient age or donor type, a program cannot inactivate its membership status if it decides to cease performing transplants for a component. There are currently no expectations outlined for programs that voluntarily cease performing a specific type of

transplant. Even though programs cease performing a certain type of transplant and do not inactivate their program status, certain patients may be impacted by this decision and should receive notification which provides detailed information and options.

A focus group comprised of MPSC, Transplant Administrators Committee, and Patient Affairs Committee members met to discuss modifications to the Bylaw requirements for patient notification of cessation of components of a program and of inactivation of waiting lists. This work group reviewed existing Bylaw language and observed that there were no specific notification content or timing requirements for either periods of waiting list inactivation or voluntary cessation of a program component. The proposed bylaw language will provide clear expectations of notification responsibilities for transplant programs and provide the MPSC with more guidance for monitoring functional inactivity.

While these modifications are an improvement, transplant programs may feel additional burden since they must notify candidates during periods of cessation of a program component and within specific time periods for waiting list inactivation. This added burden may be in the form of increased patient questions and calls regarding correspondence from the transplant program, or an increased financial burden related to the costs of providing written notification to all candidates and affected patients. Additionally, transplant programs may be required to respond to MPSC inquiries regarding waiting list inactivation and cessation.

Details of the Proposal:

This proposal will require transplant programs to notify patients when one of more of the following conditions are met: 15 or more consecutive or 28 or more cumulative days of waiting list inactivation.

Programs must include the following information in the patient notification letters:

- The reason for the inactivity
- The expected length of time that the waiting list will be inactive
- The explanation that during the period of inactivity, organs cannot be accepted on the candidate’s behalf at this transplant program
- The options available to the candidates during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
- How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
- A copy of the Patient Information Letter
- If written notice is required because a Transplant Program exceeded the inactive waiting list threshold due to *cumulative* periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation

Programs must provide notice within the periods defined in the table below:

For...	Written Notice Must be Provided...
Periods of waiting list inactivation scheduled at least 30 days in advance	30 days before inactivity begins.
Periods of waiting list inactivation scheduled less than 30 days in advance	No more than 7 days following the initial date of waiting list inactivation.

Any periods of waiting list inactivation related to a cumulative period of inactivation	No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.
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The following is an example of a program reaching cumulative waiting list inactivation of 28 days or more in one 365 day Period:

Example: Program reaching cumulative waiting list inactivation of 28 days or more in one 365 day Period					
	Center A	Start Date	Consecutive # of Days Inactive	# of Days WL inactive for Review Period	Running total: Cumulative # of days
Period 1	Instance 1 of WL Inact	1/10/11	3	3	3
	Instance 2 of WL Inact	3/15/11	7	7	10
	Instance 3 of WL Inact	6/27/11	7	7	17
	Instance 4 of WL Inact	8/20/11	4	4	21
	Instance 5 of WL Inact	11/22/11	13	13	34
	Instance 6 of WL Inact	12/22/11	7	7	41
	Total # of Cumulative Days WL Inactivated in Period 1				41
Within Instance 5, the program reaches the 28 day threshold and must notify patients no later than 12/5/11 (7 days following Day 13) and must also notify for any subsequent periods when the threshold is surpassed; therefore in Instance 6, the program must again notify patients no later than 12/29/11 (7 days following Day 7).					

This proposal would also require transplant programs that cease a component of the program to:

- Notify all patients affected by the cessation at least 30 days prior to, but no later than 7 days after cessation of a program component. Notification letters must include:
 - The reason for cessation
 - The explanation that organs cannot be accepted on the candidate's behalf during period of cessation
 - The options to transfer to another program
 - The phone number for the transplant program's administrative office to assist with transfer to another program

Supporting Evidence and/or Modeling:

UNOS staff routinely receive questions from transplant programs regarding patient notifications of waiting list inactivation and program component cessation; therefore, the MPSC wanted to add clarity to the existing Bylaws.

Expected Impact on Living Donors or Living Donation:

This proposal impacts living donation in situations where the transplant program has ceased performing living donor transplants. This proposal would require that transplant programs inform all affected parties of the decision for cessation of program components and available options for living donors and potential living donors.

Expected Impact on Specific Patient Populations:

This proposal impacts pediatric or adult patients in situations where the program has ceased performing pediatric or adult transplants. This proposal would require that transplant programs inform all affected parties of the decision for cessation of a program component and available options.

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

This proposal addresses the strategic plan goal of promoting the efficient management of the OPTN. This proposal clarifies existing bylaw language regarding functional inactivity and the MPSC's review of transplant program performance. Member responsibilities and expectations are clearly defined in the proposal and will result in improved interpretation of and compliance with Bylaw requirements.

Plan for Evaluating the Proposal:

The MPSC will continue to monitor the frequency of waiting list inactivation and trends. The MPSC will evaluate the responses to its inquiries to active programs with inactive waiting lists according to the proposed modifications, both those greater than 14 consecutive days and 28 or more cumulative days. The MPSC will also evaluate notifications to patients affected by the cessation of a portion of a program.

Additional Data Collection:

This bylaw proposal should not result in additional data collection.

Expected Implementation Plan:

This proposal will be considered by the Board of Directors in June 2013. If approved, the changes will be effective September 1, 2013.

The current Bylaws require transplant programs to notify candidates in writing of periods when their waiting list default is set to inactive for 15 or more consecutive days or 28 or more cumulative days in a 365 day period. If this proposal is approved, these notifications must contain all of the required elements and must be sent within the timeframes outlined in the proposal details section above.

There are currently no requirements for notification of voluntary cessation of a transplant program subsection or component. If this proposal is approved, transplant programs must notify the OPTN in writing and send a representative copy of the notification and a list of all patients that received the notification. Notifications must contain all of the required elements and must be sent within the timeframes outlined in the proposal details section above.

The MPSC will continue to monitor transplant program compliance with requirements contained in the proposal.

Compliance Monitoring:

Concerning waiting list inactivation, the MPSC Performance Analysis and Improvement Subcommittee will continue to monitor compliance with bylaw requirements as part of its existing review of functional inactivity. UNOS will review a list of all Members that ever inactivated their waiting list for one or more of the following time periods: 15 or more consecutive days or 28 or more cumulative days over a rolling 365 day period. (This is an existing report.) UNOS will then send a letter to these programs and request confirmation that candidates were notified of the period(s) of waiting list inactivation, in compliance with the proposed content and timing requirements.

The MPSC will also monitor programs that voluntarily cease performing a specific type of transplant. UNOS will request confirmation that the affected groups, outlined in the proposed language, were notified of the cessation, in compliance with the proposed requirements.

UNOS already works with Members that voluntarily inactivate a transplant program or cease performing a specific type of transplant, and help these transplant programs with the transition. If a Member is found to be noncompliant with the Bylaw, the Member will be referred to the MPSC. The Committee will follow its normal process for investigation and may take action as defined in Appendix L of the Bylaws.

Policy or Bylaw Proposal:

The MPSC voted on December 7, 2011, to distribute the following proposed modifications to the Bylaws for public comment, by a vote of 23 For, 8 Against, 0 Abstentions.

The Modifications to Appendix D, Section D.9 and Appendix K, Section 1 appear below with new language underlined and deleted language marked with ~~strikethroughs~~.

**Appendix D:
Membership Requirements for Transplant Hospitals and Transplant Program**

No changes to Sections D.1 through D.10.

D.9 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active. Transplant program functional activity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC. For purposes of these Bylaws, functional inactivity is defined as *any* of the following:

1. The inability to serve potential candidates, candidates, ~~or recipients~~, potential living donors, or living donors for a period of 15 or more consecutive days.
2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.
3. The failure to perform a transplant during the periods defined in the table below:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

Given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements for functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

B. Requirements of Functional Inactivity

A transplant program must provide written notice to candidates if it does *either or both* of the following:

1. Inactivates its waiting list or is unable to perform transplants for 15 or more consecutive days.
2. Inactivates its waiting list or is unable to perform transplants for 28 or more cumulative days over any 365 consecutive day period.

A Transplant Program must provide written notice *each* time it reaches either of the inactive waiting list thresholds listed above. Written notice must include *all* of the following:

1. The reason for the inactivity
2. The expected length of time that the waiting list will be inactive
3. The explanation that during the period of inactivity, organs cannot be accepted on the candidate's behalf at this transplant program
4. The options available to the candidates during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
5. How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
6. A copy of the UNOS Patient Information Letter

Note: If written notice is required because a Transplant Program exceeded the inactive waiting list threshold due to cumulative periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation.

Written notice must be provided within the periods defined in the table below:

<u>For...</u>	<u>Written Notice Must be Provided...</u>
<u>Periods of waiting list inactivation scheduled at least 30 days in advance</u>	<u>30 days before inactivity begins.</u>
<u>Periods of waiting list inactivation scheduled less than 30 days in advance</u>	<u>No more than 7 days following the initial date of waiting list inactivation.</u>
<u>Any periods of waiting list inactivation related to a cumulative period of inactivation</u>	<u>No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.</u>

Copies of all written notifications must be retained and be provided to the OPTN Contractor on request.

C. Review of Member Functional Inactivity

The MPSC may also require, at its discretion, that the member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC.

The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to 12 months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than 12 months, the member should relinquish designated transplant program status as required in these Bylaws.

The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's inactivity.

No Changes to Sections K.2 through K.7.

Appendix K: Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

K.1 Transplant Program Inactivity

Transplant programs must remain active in transplantation to maintain membership in the OPTN. There are two types of member inactivity:

1. Short-term Inactivity
2. Long-term Inactivity

A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- The inability to meet functional activity requirements.
- Temporarily lacking required physician or surgeon coverage.
- A substantial change in operations that requires an interruption in transplantation.

For more information about the functional activity requirements for transplant programs, see *Appendix D, Section D.9: Review of Transplant Program Functional Activity* of these Bylaws.

A. Program Component Cessation

Programs that cease performing a specific type of transplant (e.g. the living donor component of a transplant program, or cessation of only pediatric or only adult transplants in a transplant program that performs both), must notify every patient affected by the cessation, including:

- Potential candidates, including those currently in the referral or evaluation process
- All candidates registered on the waiting list
- Potential living donors, including those currently in the referral process, in the evaluation process, or awaiting donation

For more information about the notification content and timing requirements, see *Appendix K, Sections K.3-4:* of these Bylaws.