

# OPTN/UNOS Policy Notice

## Updating the OPTN Definition of Transplant Hospital

<b>Sponsoring Committee:</b>	<b>Membership and Professional Standards</b>
<b>Policy/Bylaws Affected:</b>	<b>OPTN Bylaws Appendices D.2 (Designated Transplant Program Requirement), D.11.F (Veteran’s Administration (VA) Dean’s Committee Hospitals), and M (Definitions)</b>
<b>Public Comment:</b>	<b>August 2016</b>
<b>Effective Date:</b>	<b>Pending implementation and notice to members</b>

### Problem Statement

We have not modified the existing definition of a transplant hospital in OPTN/UNOS Policy and Bylaws since the original implementation date in 1986. The evolving structure of hospitals and medical systems has made the current definition too simplistic and vulnerable to interpretation. Specifically, the current definition does not identify the basic accountable unit in which organ transplantation occurs. This has made it difficult for the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to make meaningful, accurate, and conclusive assessments regarding transplant program membership applications, transplant program performance outcomes and transplant program compliance with OPTN obligations.

### Summary of Changes

There is now a list of characteristics to define what a transplant hospital is. The new definition allows members to perform transplants in more than one location, provided the locations meet the following requirements:

- Transplant ORs must have common executive leadership and governance oversight, demonstrated to satisfaction of the OPTN
- Transplant ORs must be preemptively documented with the OPTN
- Transplant ORs must also meet one of the following criteria:
  - 1) Be within a “contiguous campus”
  - 2) Be within a one-mile walking distance of the main hospital address
  - 3) Be approved at the discretion of the OPTN

Under this new definition, only one member will be allowed per campus unless the other member is a children’s or Veterans Affairs (VA) hospital.

### What Members Need to Do

After UNOS has completed necessary programming, it will provide notice to all transplant hospitals. Within 60 days of the notification, all transplant hospitals will be expected to notify UNOS of the transplant hospital’s intention to either remain recognized as the current, single transplant member; to separate its current membership into more than one transplant hospital member, or merge its existing membership with other existing transplant hospital members. In addition, all transplant hospitals will be expected to provide the following information:

- Type of campus arrangement (i.e., contiguous campus, one mile walking distance radius)
- Transplant operating room documentation, including:

- Maps that illustrate the transplant hospital campus and the location of each operating room facility
- Building name and address
- Floor number
- Unit identifier

No additional action is required of transplant hospitals that submit complete information and qualify as a single transplant hospital using either the “contiguous campus” or the “one-mile walking distance” geographical considerations.

Transplant hospitals with operating rooms beyond the established geographic boundaries may be asked to provide additional information for the MPSC’s consideration. The MPSC may also request that the transplant hospital participate in an informal discussion. During the discussion, the MPSC will expect the transplant hospital to explain their organization and why the MPSC should consider an exception to the explicit boundaries used to define a transplant hospital.

To allow transplant hospital members sufficient time to meet the new requirements, the OPTN will not implement the approved Bylaws definition for at least 12 months from the date UNOS provides notice to transplant hospital members.

### Affected Policy Language

New language is underlined (example) and language that is removed is struck through (~~example~~).

## 1 **Appendix D: Membership Requirements for Transplant** 2 **Hospitals and Transplant Programs**

### 3 **D.2 Geographic Requirements for Transplant Hospitals**

4 A transplant hospital must be entirely within a single donation service area (DSA) and all of its operating  
5 room facilities used for organ transplantation must be under common executive leadership and  
6 governance oversight, demonstrated to the satisfaction of the OPTN.

7  
8 All transplant hospital operating rooms where transplants are performed must also meet at least *one* of  
9 these requirements:

- 10 ▪ Are within a geographically contiguous campus
- 11 ▪ Are within a one mile walking distance from the main hospital’s physical address

12 Each operating room that the transplant hospital may use to perform transplants must be documented  
13 with the OPTN prior to its use for transplant surgery. This operating room documentation requirement  
14 includes any additional transplant operating rooms that are not listed on the transplant hospital’s initial  
15 application. Documentation of the operating rooms where organ transplants may occur must at least  
16 include *all* of the following:

- 17 1. Maps that illustrate the transplant hospital campus and the location of each operating room facility
- 18 2. Building name and address
- 19 3. Floor number
- 20 4. Unit identifier

21 Transplant hospitals that do not meet these requirements will not be approved as a single transplant  
22 hospital and will require separate OPTN memberships, unless the transplant hospital is approved  
23 according to *D.2.A: Approval of Transplant Hospitals with Operating Rooms Beyond the Established*  
24 *Geographic Boundaries*. Any application recommended for rejection by the MPSC or the Board of  
25 Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due*  
26 *Process* of these Bylaws.

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**A. Approval of Transplant Hospitals with Operating Rooms Beyond the Established Geographic Boundaries**

As long as the hospital is able to fulfill all other requirements established in these Bylaws, the OPTN may approve transplant hospitals that have operating rooms used for transplantation beyond the geographical boundaries established above. The hospital may submit an application to the OPTN to consider its specific circumstances if all of the following conditions are met:

1. The hospital provides a written explanation detailing the mitigating circumstances that necessitate designation of a single transplant hospital or preclude registration of a second transplant hospital. The written explanation must at least address the following:
  - a. Transplant patient safety
  - b. Impact on patient access
  - c. Organ utilization
2. The hospital provides a written plan for transplant patient care, including evidence that all necessary services and support will be available to transplant recipients.
3. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and grant interim approval, according to Appendix A.3: Applying for Membership in the OPTN. Interim approvals are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a transplant hospital.
- Effective temporarily, pending final decision by the MPSC or Board of Directors.

**B. Multiple Transplant Hospitals Citing the Same Campus Boundaries**

A transplant hospital campus may only be associated with one transplant hospital unless the other transplant hospital is either of the following:

- Has approval as a transplant hospital in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Primarily serves pediatric patients. Transplant hospitals that annually perform, or intend to perform, 50 percent or more of their total transplants in patients less than 18 years of age will be identified as primarily serving pediatric patients.

**C. Review of Pediatric Transplant Activity at Transplant Hospitals that Share a Campus**

Transplant hospitals that primarily serve pediatric patients, and that share a campus with another transplant hospital, will be reviewed periodically by the MPSC to verify that it performed 50 percent or more of its transplants in patients less than 18 years of age during the previous 12 months. Any transplant hospital that is identified as not meeting this 50 percent threshold in any 12 month period will have the opportunity to explain its pediatric inactivity in a report to the MPSC.

As part of its review of pediatric transplantation activity at transplant hospitals that share a campus, the MPSC may require that the member participate in an informal discussion. 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

72 participates in an informal discussion with the MPSC is entitled to receive a summary of the  
73 discussion.

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75 The MPSC may recommend that a transplant hospital sharing a campus with another transplant  
76 hospital inactivate due to one hospital no longer primarily serving pediatric patients. If the hospital  
77 fails to inactivate when the MPSC recommends it do so, the MPSC may recommend that the  
78 Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due*  
79 *Process* of these Bylaws.

## 81 **D.23 Designated Transplant Program Requirement**

82 In order to receive organs for transplantation, a transplant hospital member must have current approval  
83 as a designated transplant program for at least one organ. A transplant hospital can only have one  
84 designated transplant program for each respective organ. Designated transplant programs must meet at  
85 least *one* of the following requirements:

- 86 ▪ Have approval as a transplant program by the Secretary of the U.S. Department of Health and  
87 Human Services (HHS) for reimbursement under Medicare.
- 88 ▪ Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense,  
89 or other Federal hospital.
- 90 ▪ Qualify as a designated transplant program according to the membership requirements of these  
91 Bylaws.

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93 The OPTN does not grant designated transplant program approval for any type of vascularized organ  
94 transplantation for which the OPTN has not established specific criteria. In order to perform vascularized  
95 organ transplantation procedures for which there are no OPTN-established criteria, including multi-  
96 visceral transplants, a hospital must be a transplant hospital member and have current approval as a  
97 designated transplant program for at least one of the organ types involved in multi-visceral transplant. In  
98 the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a  
99 designated liver transplant program.

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101 *[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will*  
102 *also be changed as necessary.]*

## 104 **D.142 Additional Transplant Program Requirements**

### 105 **~~F. Veteran's Administration (VA) Dean's Committee Hospitals~~**

106 ~~VA Hospitals that are Dean's Committee Hospitals and share a common university based~~  
107 ~~transplant team, do not need to submit a separate membership application to the OPTN~~  
108 ~~Contractor, but may be considered members under the university program with which they are~~  
109 ~~affiliated.~~

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111 ~~Independent VA Hospitals, or VA Hospitals that are not Dean's Committee Hospitals sharing a~~  
112 ~~common university based transplant team, must submit an application and be approved for OPTN~~  
113 ~~membership in order to receive organs for transplantation.~~

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115 *[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will*  
116 *also be changed as necessary.]*

## 118 **Appendix M: Definitions**

### 119 **Geographically Contiguous Campus**

120 The physical area within an enclosed boundary drawn on a map that exclusively encompasses land and  
121 buildings owned by, or directly associated with, the hospital. Separate commercial or residential property  
122 adjacent to hospital property must be excluded from the boundary.

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