

## ***At-a-Glance***

### **Definition of a Transplant Hospital**

- **Affected Bylaws:** Bylaws Article 1.2 (Transplant Hospital Members); Bylaws Appendix M (Definitions); Policy 1.2 (Definitions)

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

The proposed changes to the transplant hospital definition are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when assessing applicant submissions for OPTN membership and transplant program designation. A transplant hospital member is currently defined by OPTN Bylaws as “a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ” and by OPTN Policy as “a health care facility in which transplants of organs are performed”. A lack of distinguishing detail in the transplant hospital definition has proven to be problematic when assessing for membership healthcare institutional configurations consisting of multiple “hospitals” performing the same organ transplants at geographically separated sites. Therefore, the goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance concerning patient safety, patient outcomes, and overall compliance with approved OPTN directives.

- **Affected Groups**

Transplant Administrators  
Transplant Data Coordinators  
Transplant Physicians/Surgeons  
PR/Public Education Staff  
Transplant Program Directors  
Transplant Social Workers  
Organ Recipients  
Organ Candidates  
Living Donors  
Donor Family Members  
General Public

- **Number of Potential Candidates Affected**

This proposal indirectly affects all patients in need of an organ transplant.

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

The transplant hospital definition reviewed in this proposal is critical for the MPSC to execute its responsibilities of assessing transplant hospitals for transplant safety, performance, and compliance with OPTN Policy and Bylaws. As such, this proposal supports the OPTN’s Strategic Plan goals for promoting patient safety and promoting the efficient management of the OPTN. Additionally, the transplant hospital definition is foundational in meeting the requirements found in the Final Rule.

## **Definition of a Transplant Hospital**

**Affected Bylaws: Bylaws Article 1.2 (Transplant Hospital Members); Bylaws Appendix M (Definitions); Policy 1.2 (Definitions)**

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

**Public comment response period: September 29 – December 5, 2014**

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

The proposed changes to the transplant hospital definition are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when assessing applicant submissions for OPTN membership and transplant program designation. A transplant hospital member is currently defined by OPTN Bylaws as “a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ” and by OPTN Policy as “a health care facility in which transplants of organs are performed”. A lack of distinguishing detail in the transplant hospital definition has proven to be problematic when assessing for membership healthcare institutional configurations consisting of multiple “hospitals” performing the same organ transplants at geographically separated sites. Therefore, the goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance concerning patient safety, patient outcomes, and overall compliance with approved OPTN directives.

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

OPTN Policy currently defines a transplant hospital as, “a health care facility in which transplants of organs are performed,” and OPTN Bylaws define a transplant hospital member as, “a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ.” These definitions have not been modified since 1986 when they were first adopted by the OPTN Board of Directors. At that time, the OPTN’s transplant hospital definitions focused on political and membership representation considerations so that members would have an appropriate say in the development of the national transplant system and organ allocation policies.

These definitions are also important to provide clear parameters of focus for the MPSC in the execution of its responsibilities for making certain patient safety is not in jeopardy, assessing transplant hospitals for outcome performance, and monitoring compliance with OPTN expectations. The evolving structure of medical systems and hospitals has rendered current definitions of a transplant hospital too simplistic, and vulnerable to differing interpretations. For example, consider healthcare systems that include separated and dedicated facilities for pediatric patients. Arguments have been made that approval is only necessary for one transplant hospital in these scenarios, supported by the fact there is a single CMS hospital provider number (CCN) for these healthcare facilities. This perspective disagrees with the MPSC’s historical stance on this matter. In deliberating issues related to these types of questions, the MPSC has traditionally abided by the following operational definitions of a transplant hospital:

- A discrete facility where an OPTN approved member transplant hospital performs organ transplants as allowed under its organ transplant program designation and approval
- The basic measurement unit is a single site (hospital)

- A single CCN awarded to distinct and separate hospitals does not mandate OPTN approval as a single member transplant hospital

Historically, there have been a few instances that the MPSC has not held to the above principals due to intervening influences. Subsequent to these actions, the MPSC encountered unwanted consequences which could have been avoided had multiple transplant sites not been allowed to consolidate into a single member and transplant program. An actual example occurred when the MPSC was unable to identify where in a single member's group of transplant facilities possible causes existed which were contributing to transplant performance outcomes falling significantly below the member's expected threshold over multiple continuous cohorts. The same organ was being transplanted at three geographically separated facilities under a single OPTN membership and with a single organ transplant program approval. Ultimately the needed improvements were identified as being required primarily at one facility.

The MPSC often faces the issue of defining a transplant hospital. The last formal position given on the definition of a transplant hospital occurred on November 10, 2010, in a letter to HRSA in which the MPSC Chair stated *"...each transplant hospital facility, at which a same organ type transplant is being performed, must have the required organ transplant program designation approved for that facility. By adopting this principle, the OPTN, at this time, can assure accountability, transparency and monitoring for each transplant program regardless of its ownership and location."*

For the MPSC to uphold its responsibilities of assessing transplant programs in a thorough and accurate manner, it believes hospital specific data is essential regardless of how hospitals have chosen to organize themselves for business or financial purposes. Accordingly, the MPSC recommends expanding the OPTN's definition of a transplant hospital as described in this proposal to eliminate ambiguity and align OPTN Policy and Bylaws with the operational definition of a transplant hospital traditionally used by the MPSC.

The MPSC believes there are numerous strengths with this approach that benefit transplant patients, including:

- Accountability for data, outcome performances, and patient safety resides with a single location
- Since transplant problems/incidents can be pinpointed to a single point of transplant surgery only that location would require a cessation of transplantation instead of all member transplant sites, this allows for all improvement actions taken to be focused on the actual origin of concern
- More closely aligns OPTN definition of "transplant hospital" with CMS definition
- Avoids the need for patients to understand the organization of healthcare facilities relative to where they will actually be transplanted
  - Hospital listing the patient is the same site where the patient will be transplanted
  - Increased transparency with single source data eliminates the burden of sorting through pooled data to determine a single site's performance

The MPSC understands that this approach has the potential to impose some burden on members, specifically the additional cost & administrative efforts necessary for a healthcare system to operate multiple OPTN member transplant hospital operations to accommodate regulatory audits and inquiries. Nevertheless, the Committee believes the positive aspects anticipated to result from the changes outlined in this proposal outweigh the potential negative impacts. Since this

proposal aims to define formally the MPSC's operational definition of a transplant hospital, the potential, additional burden caused by these changes should be limited.

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

This new definition would apply to living donor programs as well as deceased donor programs. However, this proposal is not anticipated to have a direct impact on living donors or living donation.

**Expected Impact on Specific Patient Populations:**

This proposal has the potential to provide clarity for all transplant candidates listed, or who may be listed, at a multi-hospital healthcare facility; however, it is not anticipated to have a direct impact on any specific patient populations.

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

This proposal clarifies what are the attributes defining a transplant hospital. This definition is critical for the MPSC to execute its responsibilities of assessing transplant hospitals for transplant safety, performance, and compliance with OPTN Policy and Bylaws. As such, this proposal supports the OPTN's Strategic Plan goals for promoting patient safety and promoting the efficient management of the OPTN.

Additionally, the transplant hospital definition is foundational in meeting the requirements found in the Final Rule. Specifically, §121.10 (b)(3), which states:

§121.10 Reviews, evaluation, and enforcement

(b) *Review and evaluation by the OPTN.* (1) The OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of:

[...]

(iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.

**Plan for Evaluating the Proposal:**

The impact of this proposal is immediate and evaluation will occur in real time by the MPSC. If the proposed changes are effective, the assessment of new member and transplant program applications will have less uncertainty than they can have now. The applicants will have a clearer description of what a transplant hospital's attributes are so fewer uncertainties should exist to be addressed by the MPSC.

The MPSC fully expects to monitor the impact of these changes and then most likely revisit this subject as healthcare organizational structures continue to change.

**Additional Data Collection:**

Adoption of this proposal will not result in additional data collection.

### **Expected Implementation Plan:**

The MPSC recognizes that there will still be applicants who may not be covered with the new definition. The MPSC will add to the Evaluation Plan the following language:

A subcommittee of the MPSC will review unclear applicant submissions. The subcommittee will make a recommendation on whether the applicant meets the transplant hospital member definition for the MPSC to consider. The MPSC will submit its recommendation to the Board of Directors for consideration.

The MPSC also recognizes that upon implementation it **must** have an understanding of how currently approved transplant hospitals and its transplant programs comply with the new language. As such, the MPSC plans to review current OPTN transplant hospital members regarding their physical layouts as to exactly where organ transplant surgery is performed by organ. This review will occur within 120 days of the Board approval date. Any approved transplant hospital members identified during this review as not conforming to this definition will be given two years from the date on the OPTN notification letter to take all necessary actions to become compliant.

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and implemented on September 1, 2015. Upon Board approval of the new transplant hospital member definition all new member applicants will be reviewed and approved using the updated definition.

### **Communication and Education Plan:**

If these changes are adopted by the OPTN/UNOS Board of Directors, members will be alerted through a policy notice approximately 30 days after the meeting that the Board discussed this proposal.

### **Compliance Monitoring:**

After reviewing all OPTN transplant hospital members there is no plan to maintain an ongoing compliance monitoring process. If transplant hospital configurations change and the hospital finds itself not in compliance with the existing transplant hospital definition, transplant hospitals are expected to contact the OPTN membership department and discuss its new situation, and if necessary, make all required applications for new membership and transplant program designations.

If the MPSC becomes aware of changes in an approved transplant hospital's configuration, an inquiry will be made to the hospital and assistance will be provided as necessary for the transplant hospital to come into compliance with existing requirements.

## Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

### Article I: Membership

#### 1.2 Transplant Hospital Members

- ~~A transplant hospital member is any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.~~  
A transplant hospital member is any hospital that has current approval as a designated transplant program for at least one organ.

For the Organ Procurement Transplant Network (OPTN) to successfully meet contractual obligations to monitor member compliance, patient safety and organ allocation, the transplant hospital member must have the following characteristics:

- each organ type is only transplanted in a single, discrete geographic location
- program management occurs under a single hospital administrative structure
- a single, unified medical staff credentialed and governed under the same bylaws exists
- a single, unified nursing staff and administration exists

Organ transplant service lines, conducted separately for the same organ including adult and pediatric, with each service line's transplant surgery being performed in non-contiguous buildings are considered distinct and independent for OPTN monitoring purposes. Applicants in this situation need separate transplant hospital member and transplant program approval for each service line.

### Appendix M: Definitions

## T

#### Transplant Hospital Member

~~A membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ.~~

Any hospital that has current approval as a designated transplant program for at least one organ.

### Policy 1: Administrative Rules and Definitions

#### 1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

## T

#### Transplant hospital

~~A health care facility in which transplants of organs are performed.~~

Any hospital that has current approval as a designated transplant program for at least one organ.

**Transplant program**

A ~~component~~ specialty service group within a transplant hospital that provides transplantation of a particular type of organ.