

## *Notice of OPTN Bylaw Change*

# Enhance Transplant Program Performance Monitoring System, Phase 2 (July 2023)

<b>Sponsoring Committee:</b>	<b>Membership and Professional Standards</b>
<b>Bylaw Affected:</b>	<b><i>Appendix D, D.12.A. Transplant Program Performance</i></b>
<b>Public Comment:</b>	<b>August 3, 2021 – September 30, 2021</b>
<b>Board Approved:</b>	<b>December 6, 2021</b>
<b>Effective Date:</b>	<b>July 27, 2023</b>
	<b><i>Appendix D, D.12.A. Transplant Program Performance</i></b> <b>except adult and pediatric criteria for pre-transplant</b> <b>mortality rate ratio</b>

**Pending implementation and notice to OPTN members:**  
**Appendix D, D.12.A. Transplant Program Performance**  
**adult and pediatric criteria for pre-transplant mortality**  
**rate ratio**

### **Purpose of Bylaw Change**

Previously, the OPTN Membership and Professional Standards Committee (MPSC) has used a single metric that evaluates one phase of care, one-year post-transplant graft and patient survival, for identifying underperforming transplant programs. The MPSC recognized the need to incorporate metrics that evaluate multiple phases of transplant care to create a more holistic approach to evaluation of transplant program performance. The purpose of this bylaw change is to evaluate transplant program performance more holistically, incorporating measures that evaluate multiple aspects of transplant patient care. In developing this new system, the MPSC focused on areas that were within the OPTN's stated authority. With this bylaw change, the MPSC strived to support and collaborate with transplant programs to address performance improvement opportunities while also meeting its fiduciary responsibility to monitor member performance to identify potential patient safety issues. Finally, the MPSC wanted to develop a performance review system that would provide maximum support for the OPTN Strategic Plan, specifically increasing the number of transplants, promoting equitable access to transplantation, and fostering innovation.

### **Proposal History**

The OPTN Ad Hoc Systems Performance Committee (SPC), in its report to the OPTN Board of Directors in June 2019, provided recommendations across four areas, including performance monitoring enhancements. The SPC stated a holistic approach to the evaluation of transplant hospital and OPO performance would be beneficial and suggested developing a balanced scorecard approach that incorporated multiple metrics. Although the SPC identified metrics for possible inclusion in a scorecard,

the SPC acknowledged the need for more input and work to identify and define the appropriate metrics for scorecards. After the SPC report to the Board, the MPSC was asked to continue work on this topic. The MPSC, over a 20-month period, evaluated the measures suggested by the SPC and MPSC members and gathered input from the community and stakeholders to develop a proposal that was released for public comment in summer 2021. The proposal identified a measure for each of four phases of pre- and post-transplant patient care provided by transplant programs and established separate adult and pediatric criteria to identify clinically significant outliers that may pose a potential risk to patient health or public safety. The Board approved these bylaw revisions on December 6, 2021.

## Summary of Changes

The revised *OPTN Bylaw, Appendix D, D.12.A. Transplant Program Performance* establishes new criteria for identification of transplant programs that will enter into MPSC performance review. The MPSC will review a transplant program's performance if the transplant program meets the criteria for pre-transplant mortality rate, offer acceptance rate, 90-day post-transplant graft survival hazard ratio or 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival for either adult transplants or pediatric transplants. *OPTN Bylaw, Appendix D, D.12.A. Transplant Program Performance* is also re-organized to clarify but not substantively change, transplant program obligations to participate in the performance review process. In addition, a new section is inserted in *Appendix L: Review and Actions* that codifies the current peer review process and corresponding revisions were made to other sections within *Appendix L: Reviews and Actions* that reference peer visits. Descriptions of the new metrics have been inserted into *Appendix M: Definitions* and other administrative revisions have been made to *Appendix M: Definitions* to remove the definitions of two defunct MPSC subcommittees and revise the definition of the Scientific Registry of Transplant Recipients (SRTR).

## Implementation

On July 27, 2023, the MPSC will begin evaluating transplant programs based on the criteria for the offer acceptance rate ratio under the performance review process as provided in the revised *Appendix D.12.A. Transplant Program Performance*. The MPSC will send initial inquiries to transplant programs that meet the criteria for offer acceptance rate ratio in late July. Inquiries will request information about a transplant program's structure and staffing, procedures and protocols, quality review processes, and plans for improvement. The MPSC will review the information submitted by the program and may request that the program submit additional information about certain aspects of the program or submit a plan for quality improvement. The MPSC may also request that a member participate in additional engagement with the MPSC, such as an informal discussion or a peer visit. In rare circumstances where the MPSC identifies a potential ongoing risk to patient health or public safety, the MPSC may request that a member inactivate or withdraw a transplant program or a component of a program to mitigate the risk.

The implementation of the pre-transplant mortality rate will be no earlier than July 2024. The OPTN will provide members with notice of pending implementation of the pre-transplant mortality rate metric approximately 6 months prior to implementation.

## Affected Policy Language

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

### Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

#### D.12 Additional Transplant Program Requirements

##### A. Transplant Program Performance

*Appendix D.12.A* does not apply to VCA transplants.

The MPSC will conduct reviews of transplant program performance to identify potential risks to patient health or public safety, as evidenced by either:

1. The probability that the transplant program meets any of the following criteria is greater than 50% for adult transplants:

- a. The transplant program's offer acceptance rate ratio is less than 0.30 during a 1 year period.
- b. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year time period. For pancreas transplant programs, 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.
- c. The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year period. For pancreas transplant programs, 1-year post-transplant patient survival conditional on 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.

2. The probability that the transplant program meets any of the following criteria is greater than 50% for pediatric transplants:

- a. The transplant program's offer acceptance rate ratio is less than 0.35 during a 1 year period.
- b. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.
- c. The transplant program's 1-year post-transplant graft survival conditional on 90 day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.

If a transplant program meets either of the above criteria based on reports produced by Scientific Registry of Transplant Recipients (SRTR), it must participate in an MPSC performance review. As part of the transplant program review, the MPSC may require the member to take appropriate actions to determine if the program has demonstrated sustainable improvement including, but not limited to:

- Providing information about the program structure, procedures, protocols and quality review processes
- Adopting and implementing a plan for improvement
- Participating in an informal discussion with MPSC members as described in *Appendix M*:

### *Reviews and Actions*

- Participating in a peer visit as described in *Appendix M: Reviews and Actions*

Once a member is under transplant program performance review, the MPSC will continue to review the program until the MPSC determines that the program has made sufficient and sustainable improvements in acting to avoid risk to public health or patient safety.

If the MPSC's review determines that a risk to patient health or public safety exists, the MPSC may request that a member inactivate or withdraw a designated transplant program, or a specific component of the program to mitigate the risk. Before the MPSC requests that a member inactivate or withdraw a designated transplant program or a specific component of the program due to concerns identified during a performance review, the MPSC must offer the member an informal discussion with the MPSC, as described in *Appendix M: Reviews and Actions*.

A member's failure to fully participate in the review process or to act to avoid a risk to patient health or public safety may result in action taken under *Appendix M: Reviews and Actions*.