

At-a-Glance

Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation

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***Note:** To view the video files, you will need an .mp4 player installed on your computer. QuickTime is available free as a download at: <http://support.apple.com/downloads/#quicktime>.

- **Affected Bylaw:** Appendix J (Membership and Personnel Requirements for Combined Heart and Lung Program)

Thoracic Organ Transplantation Committee and the Membership and Professional Standards Committee (MPSC)

- The proposed change removes an OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to transplant organs for which the transplant hospital has already been approved. Aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. The combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

- **Affected Groups**
Transplant Administrators
Transplant Physicians/Surgeons
Transplant Program Directors
General Public
- **Number of Potential Candidates Affected**
There is no known impact to heart-lung transplant candidates.
- **Compliance with OPTN Strategic Goals and Final Rule**
The proposed bylaw proposal promotes the efficient management of the OPTN by reducing programming and application processing, and aligning the combined heart lung transplant program approval requirements with other multi-organ transplant programs.
- **Specific Requests for Comment**
None.

Proposal to Remove the OPTN and UNOS Bylaws for the Combined Heart-Lung Transplant Program Designation

Affected Bylaw: Appendix J (Membership and Personnel Requirements for Combined Heart and Lung Program)

Thoracic Organ Transplantation Committee and the Membership and Professional Standards Committee (MPSC)

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

Summary and Goals of the Proposal:

The proposed change removes an OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to transplant organs for which the transplant hospital has already been approved. Aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. The combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

Background and Significance of the Proposal:

In its effort to upgrade its computer system, the OPTN Contractor identified an opportunity to streamline the process for a transplant hospital to obtain a single combined heart-lung transplant program designation.

In order to perform a heart-lung transplant, current bylaws require the transplant hospital to not only have an approved heart transplant program and an approved lung transplant program, but it must also have an approved combined heart-lung transplant program. In contrast, to perform a kidney-pancreas transplant, the OPTN bylaws only require a transplant hospital to concurrently have both an approved kidney transplant program and an approved pancreas transplant program.

Current OPTN bylaws require the transplant hospital to submit the names of a primary transplant surgeon and physician for the heart-lung program. Typically, the names reported to the OPTN Contractor are identical to those that qualified the transplant hospital for approval of its individual heart and lung transplant programs. Other than submitting key heart-lung personnel applicant information, there are no additional requirements for transplant hospitals to qualify for the single combined heart-lung transplant program designation.

The removal of the combined heart-lung transplant program designation in the bylaws would reduce the paperwork that a transplant hospital would have to complete, as long as the transplant hospital is already approved for both heart and lung transplant programs individually. The administrative burden on the OPTN contractor would also be reduced, as the OPTN Contractor tracks program and outcome information for combined heart-lung transplant programs separately in its database.

The initial indication from the Centers for Medicare and Medicaid Services (CMS) is that the proposed bylaw change is reasonable, and one which the CMS can incorporate into its transplant program designation regulations.

The MPSC and the Thoracic Committee voted in favor of the proposal and submitting the bylaw changes for public comment. The MPSC voted in July, 2012 as follows: 32-supported; 1-opposed; and, 2-abstained. The Thoracic Committee voted in July, 2012 as follows: 19-supported; 0-opposed; and, 0-abstained.

Supporting Evidence and/or Modeling:

In assessing whether to retain the combined heart-lung transplant program designation, it was agreed that the OPTN bylaws should be amended so that transplant hospitals are not unnecessarily burdened to submit paperwork for approval of a separate program specifically to perform combined organ transplants when approval has already been obtained for heart and lung transplant programs individually.

Administrative costs for operating the OPTN will also be removed. Currently, it takes 50 hours of staff and MPSC resource commitment to process and approve each heart-lung program. The MPSC and Thoracic Committee expect that following implementation, the MPSC would spend zero hours annually processing and monitoring combined heart-lung programs. The MPSC and Thoracic Committee also expect to find IT resource savings because additional organ transplant programs will not need to be programmed or maintained in the Chrysalis system. This approach would also remove costs for coding each of the combined transplant program approvals, and help to ensure currency and accuracy of transplant program data.

Expected Impact on Living Donors or Living Donation:

None

Expected Impact on Specific Patient Populations:

There is no known impact to heart-lung transplant candidates.

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

The proposed bylaw proposal promotes the efficient management of the OPTN by reducing programming and application processing, and aligning the combined heart-lung transplant program approval requirements with other multi-organ transplant programs.

Plan for Evaluating the Proposal:

The MPSC and Thoracic Committee will evaluate whether the removal of the combined heart-lung transplant program designation creates efficiency in OPTN operations. The MPSC will compare the hours spent processing and monitoring combined heart-lung transplant programs in the three years prior to the removal of this requirement, to the hours spent processing and monitoring combined heart-lung transplant programs in each year following implementation of the removal.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The OPTN/UNOS Board of Directors will consider this proposal in June, 2013. If approved by the OPTN/UNOS Board of Directors, the OPTN Contractor will implement the bylaw change pending programming. Upon approval, transplant programs will no longer be required to submit a program application or key personnel changes for combined heart-lung programs.

Compliance Monitoring:

This proposal will not affect monitoring of heart and lung programs. However, UNOS will no longer review applications for nor designate heart-lung programs.

Bylaw Proposal:

The modifications to Appendix J, Section D.9 appear below with deleted language marked with strikethroughs.

~~Appendix J:~~

~~Membership and Personnel Requirements for Joint Heart and Lung Programs~~

~~A designated heart and lung transplant program must have current approval as a designated heart transplant program and a designated lung transplant program as described in:~~

- ~~■ Appendix H: Membership and Personnel Requirements for Heart Transplant Programs~~
- ~~■ Appendix I: Membership and Personnel Requirements for Lung Transplant Programs~~

~~Designated heart and lung transplant programs must also meet general membership requirements, which are described in Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs of these Bylaws.~~

~~For more information on the application and review process, see Appendix A: Membership Application and Review of these Bylaws.~~

~~J.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician~~

~~A heart and lung transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.~~

~~The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below in Sections J.2 and J.3. The primary surgeon and physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see Appendix D, Section D.5.B: Surgeon and Physician Coverage of these Bylaws.~~

~~J.2 Primary Heart and Lung Transplant Surgeon Requirements~~

~~A designated heart and lung transplant program must have on site a qualified transplant surgeon who meets the requirements for primary heart transplant surgeon or primary lung transplant surgeon as defined in these Bylaws.~~

J.3 — Primary Heart and Lung Transplant Physician

~~A designated heart and lung transplant program must have on site a qualified transplant physician who meets the requirements for primary heart transplant physician or primary lung transplant physician as defined in these Bylaws.~~