

DATE: May 20, 2025

TO: Daniel Cline, Office of Management and Budget Desk Officer

FROM: Samantha Miller, Health Resources and Services Administration
Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) Health Systems Bureau requests approval for changes to membership forms for the Organ Procurement and Transplantation Network (OPTN) Application Form (OMB #0915-0184, expiration date December 31, 2025).

Purpose: The purpose of this request is to make changes to select OPTN membership forms to maintain current and effective data collection. The OPTN Board of Directors approved changes to OPTN business membership requirements in December 2024. As a result, one form must be updated to align the application with the new requirements. The requirements are less restrictive and will not increase member burden or add new questions to the form.

Additionally, the OPTN Board of Directors approved the separation of the prior OPTN bylaws into two distinct documents: Bylaws and Management and Membership Policies. All references to OPTN Bylaws in the membership forms must be revised to accommodate this update. Specific bylaw or policy numbers will be removed to account for revisions within the OPTN documents.

These updates would align the applications with membership requirements and eliminate outdated titles for OPTN governance documents. This memo explains the non-substantive changes and provides a supporting rationale.

Changes: The below table includes the instrument that received the change, the variable name of the location of the alteration and/or addition, a description of the change, and the rationale for the change. Attached are the impacted membership application forms, Attachments 1-44. Two versions of each form have been provided, one with proposed changes tracked through redlines for reference and a clean copy of the form with the proposed changes incorporated.

The overall scope of change to the membership applications is minimal, representing an update of existing content. These updates do not impose additional data or documentation submission from OPTN members.

Time Sensitivity: The OPTN data collection changes must be completed in a timely manner so that corrected applications can be provided to OPTN members and prospective members. Approval of these changes is requested by April 30, 2025.

Burden: The non-substantive changes included herein do not substantially change the estimated reporting burden for current and prospective OPTN members.

PROPOSED NON-SUBSTANTIVE CHANGES:

Instrument	Variable*	Change implemented	Rationale
2A: OPTN Membership Application for Transplant Hospitals and Programs	Pages Hospital – 3, 5, 7, 12, 13	Removed references to “bylaws;” Replaced specific bylaw appendix reference with actual OPTN membership requirement language; removed specific policy numbers and titles.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2B: OPTN Membership Application for Kidney Transplant Programs	Pages Kidney – 3, 12, 18, 19, 32, 35, 36, 38, 39, 41	Removed references to “bylaws;” removed specific bylaw numbers and titles; removed specific policy numbers and titles.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2C: OPTN Membership Application for Liver Transplant Programs	Pages Liver – 3, 11, 32, 35, 38, 42	Removed references to “bylaws;” removed specific bylaw numbers and titles; removed specific policy numbers and titles.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.

Instrument	Variable*	Change implemented	Rationale
2D: OPTN Membership Application for Pancreas Transplant Programs	Pages Pancreas – 3, 11, 12, 25, 28	Removed references to “bylaws;” removed specific bylaw numbers and titles.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2E: OPTN Membership Application for Heart Transplant Programs	Pages Heart – 3, 25, 29, 32	Removed references to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2F: OPTN Membership Application for Lung Transplant Programs	Pages Lung – 3, 29, 33	Removed references to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2G: OPTN Membership Application for Islet Transplant Programs	Pages Islet – 4, 9, 10, 22	Removed references to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2H: OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	Pages VCA – 3, 16, 18, 22, 26, 28	Removed references to “bylaws;” removed specific bylaw numbers and titles; removed specific policy numbers and titles.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.

Instrument	Variable*	Change implemented	Rationale
2I: OPTN Membership Application for Intestine Transplant Programs	Pages Intestine – 3, 22	Removed references to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2J: OPTN Membership Application for Organ Procurement Organizations	Pages OPO – 8, 9	Removed references to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2K: OPTN Membership Histocompatibility Laboratory Application	Pages Histo – 3, 5, 11, 13, 14, 15	Removed references to “bylaws;” removed specific bylaw numbers and titles; removed specific policy numbers and titles.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2L: OPTN Representative Form	Page OPTN Rep – 4	Removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2M: OPTN Medical/Scientific Membership Application	Page Med/Sci – 4	Removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.

Instrument	Variable*	Change implemented	Rationale
2N: OPTN Public Organization Membership Application	Page Public – 4	Removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2O: OPTN Business Membership Application	Page Business – 3, 4	Aligned application with OPTN business membership requirement updates; removed questions 1 and 2 and updated the word “two” to “one;” removed reference to “bylaws.”	The changes make OPTN business membership less restrictive, as it will soon be required to be a member to obtain access to the OPTN Computer System. Changes include removal of the requirement to be “in operation for at least one year” and reduction of the number of required “active OPTN transplant hospital, OPO, or histocompatibility laboratory members” the applicant is involved in commercial activities with from “two or more” to “one or more;” form updates must happen to allow for security changes to be implemented. Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2P: OPTN Individual Membership Application	Page Individual – 4	Removed reference to “bylaws”	Maintains accurate information for members; Removes specific references that may become outdated due to governance document updates; Allows for future naming/numbering updates without impacting forms.

Instrument	Variable*	Change implemented	Rationale
2Q: Primary Program Administrator Form	Page PPA – 3	Removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2R: Primary Data Coordinator Form	Page PDC – 3	Removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2S: Additional Surgeon and Physician Request Form	Page Additional – 3	Removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2T: Hope Act Variance Request Form	Pages Hope Act – 3, 4, 5	Removed references to “bylaws;” removed specific numerical references for governance documents; removed specific policy number.	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.
2U: Kidney Paired Donation Pilot Program (KPDPP) Contact Update Form	Page KPDPP – 2, 3	Removed “UNOS” and replaced with “OPTN;” removed reference to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.

Instrument	Variable*	Change implemented	Rationale
2V: OPTN Membership Application Surgeon or Physician Log	Pages 4, 10	Removed references to “bylaws.”	Maintains accurate information for members; removes specific references that may become outdated due to governance document updates; allows for future naming/numbering updates without impacting forms.

*Page numbers align with the Redline version of each form

Attachments:

- A. OPTN Membership Application for Transplant Hospitals and Programs
- B. OPTN Membership Application for Kidney Transplant Programs
- C. OPTN Membership Application for Liver Transplant Programs
- D. OPTN Membership Application for Pancreas Transplant Programs
- E. OPTN Membership Application for Heart Transplant Programs
- F. OPTN Membership Application for Lung Transplant Programs
- G. OPTN Membership Application for Islet Transplant Programs
- H. OPTN Membership Application for VCA Transplant Programs
- I. OPTN Membership Application for Intestine Transplant Programs
- J. OPTN Membership Application for Organ Procurement Organizations
- K. OPTN Membership Histocompatibility Laboratory Application
- L. OPTN Representative Form
- M. OPTN Medical Scientific Membership Application
- N. OPTN Public Organization Membership Application
- O. OPTN Business Membership Application
- P. OPTN Individual Membership Application
- Q. Primary Program Administrator Form
- R. Primary Data Coordinator Form
- S. Additional Surgeon and Physician Request Form
- T. Hope Act Variance Request Form
- U. Kidney Paired Donation Pilot Program (KPDPP) Contact Update Form
- V. OPTN Membership Application Surgeon or Physician Log