



DATE: October 16, 2023

TO: Daniel Cline, OMB Desk Officer

FROM: Joella Roland, HRSA Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) Division of Transplantation requests approval for non-substantive changes to the Membership Forms for the Organ Procurement and Transplantation Network (OPTN) information collection package (OMB 0915-0184 expiration date 12/31/2025).

Purpose: The purpose of this request is to make changes to select OPTN membership forms in order to maintain current and effective data collection. This memo explains the changes and supporting rationale.

This package consists of the membership application documents used to collect information required for membership in and designation of transplant programs by the OPTN. The previous information collection package was approved in January 2023.

Through the previous package, the OPTN Membership Applications underwent a significant overhaul to the design of the forms to better align with the OPTN bylaws and eliminate redundancies. After the package was approved and the updated forms were put into use, it was identified that as a result of this major revision effort. Some areas within the embedded instructions needed further clarification and one typographical error was identified. In addition, a non-substantive OPTN bylaw correction was approved by the OPTN Board of Directors in December 2022. As a result, one OPTN Membership Application Form (OPTN Membership Application for Kidney Transplant Programs) must be updated to reflect the bylaw change. The update was not made in the current package because the bylaw change occurred while the package was with OMB for review.

HRSA would like to rectify these non-substantive changes by using a change memo in 2023.

Time Sensitivity: The OPTN data collection changes must be completed in a timely manner so that improved and corrected applications can be provided to OPTN members and prospective members. Approval of these changes is requested by October 30, 2023.

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

PROPOSED CLARIFICATIONS AND NON-SUBSTANTIVE CHANGES FOR OPTN MEMBERSHIP FORMS:

Please note that the page references coincide with the redlined versions of the original forms.

Table A

Instrument	Variable	Change implemented	Rationale
OPTN Membership Application for Kidney Transplant Programs	Page 32, Instructions for Pediatric Component – Change/Addition	Added language stating that primary pediatric kidney surgeons and physicians must meet both primary and pediatric primary OPTN bylaw requirements; and modified language referencing which sections of the application must be completed	This is to make sure the application clearly explains all requirements and all parts of the application that must be completed by applicants to demonstrate OPTN bylaw requirements are met.
OPTN Membership Application for Kidney Transplant Programs	Page 33, Part 7A: Primary Pediatric Kidney Transplant Surgeon Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Kidney Transplant Programs	Page 34, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Kidney Transplant Programs	Page 35, Part 7C: Conditional Approval for a Pediatric	Removed “the corresponding pathway section in” from instructions for question 2 of Option A. Changed “kidney	The part referenced must be completed by the applicant in full, not just the pathway section. Since these instructions

Programs	Component – Removal/Change	application” to “this application.”	are within the kidney application, it is clearer to say, “this application” than “kidney application.”
OPTN Membership Application for Liver Transplant Programs	Page 12, Part 5: Primary Liver Transplant Surgeon Requirements – Change	Changed “transplants” to “procurements” for Part 5A, question 2.	This is a typo – the OPTN bylaw requirement relates to procurement experience, not transplant experience.
OPTN Membership Application for Liver Transplant Programs	Page 34, Instructions for Pediatric Component – Change/Addition	Added language stating that primary pediatric liver surgeons and physicians must meet both primary and pediatric primary OPTN bylaw requirements, and modified language referencing which sections of the application must be completed.	This is to make sure the application clearly explains all requirements and all parts of the application that must be completed by the applicant to demonstrate requirements are met.
OPTN Membership Application for Liver Transplant Programs	Page 35, Part 8A: Primary Pediatric Liver Transplant Surgeon Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Liver Transplant Programs	Page 37, Part 8B: Primary Pediatric Liver Transplant Physician Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Liver Transplant Programs	Page 38, Part 8C: Conditional Approval for a Pediatric Component – Removal/Change	Removed “the corresponding pathway section in” from instructions for question 2 Option A. Changed “liver application” to “this application.”	The part referenced must be completed by the applicant in full, not just the pathway section. Since these instructions are within the liver application, it is clearer to say, “this application” than “liver application.”
OPTN Membership Application for Pancreas Transplant	Page 25, Instructions for Pediatric Component –	Added language stating that primary pediatric pancreas surgeons and physicians must meet both primary and pediatric primary OPTN bylaw	This is to make sure the application clearly explains all OPTN bylaw requirements and all parts of the application that must be completed by the

Programs	Change/Addition	requirements, and modified language referencing which sections of the application must be completed	applicant to demonstrate requirements are met.
OPTN Membership Application for Pancreas Transplant Programs	Page 26, Part 7A: Primary Pediatric Pancreas Transplant Surgeon Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Pancreas Transplant Programs	Page 27, Part 7B: Primary Pediatric Pancreas Transplant Physician Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Heart Transplant Programs	Page 25, Instructions for Pediatric Component – Change/Addition	Added language stating that primary pediatric heart surgeons and physicians must meet both primary and pediatric primary OPTN bylaw requirements, and modified language referencing which sections of the application must be completed.	This is to make sure the application clearly explains all requirements and all parts of the application that must be completed by the applicant to demonstrate requirements are met.
OPTN Membership Application for Heart Transplant Programs	Page 26, Part 7A: Primary Pediatric Heart Transplant Surgeon Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Heart Transplant Programs	Page 27, Part 7B: Primary Pediatric Heart Transplant Physician Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 3.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Heart Transplant Programs	Page 29-30, Part 7C: Conditional Approval for a Pediatric Component – Removal/Change	Removed “the corresponding pathway section in” from instructions for question 2 of both Option A and Option B. Changed “heart application” to “this application.”	The part referenced must be completed by the applicant in full, not just the pathway section. Since these instructions are within the heart application, it is clearer to say, “this application” than “heart

			application.”
OPTN Membership Application for Lung Transplant Programs	Page 29, Instructions for Pediatric Component – Change/Addition	Added language stating that primary pediatric lung surgeons and physicians must meet both primary and pediatric primary OPTN bylaw requirements, and modified language referencing which sections of the application must be completed.	This is to make sure the application clearly explains all OPTN bylaw requirements and all parts of the application that must be completed by the applicant to demonstrate requirements are met.
OPTN Membership Application for Lung Transplant Programs	Page 30, Part 7A: Primary Pediatric Lung Transplant Surgeon Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Lung Transplant Programs	Page 31, Part 7B: Primary Pediatric Lung Transplant Physician Requirements – Removal	Removed “the corresponding pathway section in” from instructions for question 2.	The part referenced must be completed by the applicant in full, not just the pathway section.
OPTN Membership Application for Histocompatibility Laboratories	Page 9, Part 4A: Histocompatibility Laboratory Director – Change/Addition	Added two certifications, the ACHI(S) and ACHI(F), to the options listed for Pathway 2. Changed format to bulleted list and added “Have certification as one of the following”	These certifications were added to the OPTN bylaws as certification options for this pathway as a non-substantive bylaw correction approved by the OPTN Board of Directors in December 2022. This update reflects a change in the name of the organization issuing the certification from ABHI to ACHI, as well as specific certification naming convention changes. The addition of the certification will align the application with the current OPTN bylaws.

Attachments:

1. 03_OPTN Membership Application for Kidney Programs (All changes and additions are tracked in the attached document)
2. 03_OPTN Membership Application for Kidney Programs (This is a clean document)

3. 04_OPTN Membership Application for Liver Programs (All changes and additions are tracked in the attached document)
4. 04_OPTN Membership Application for Liver Programs (This is a clean document)
5. 05_OPTN Membership Application for Pancreas Transplant Programs (All changes and additions are tracked in the attached document)
6. 05_OPTN Membership Application for Pancreas Transplant Programs (This is a clean document)
7. 06_OPTN Membership Application for Heart Transplant Programs (All changes and additions are tracked in the attached document)
8. 06_OPTN Membership Application for Heart Transplant Programs (This is a clean document)
9. 07_OPTN Membership Application for Lung Transplant Programs (This is a clean document)
10. 07_OPTN Membership Application for Lung Transplant Programs (All changes and additions are tracked in the attached document)
11. 12_OPTN Membership Application for Histocompatibility Laboratories (All changes and additions are tracked in the attached document)
12. 12_OPTN Membership Application for Histocompatibility Laboratories (This is a clean document)