

DATE: September 19, 2024

TO: Daniel Cline, OMB Desk Officer

FROM: Joella Roland, HRSA Information Collection Clearance Officer

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

Purpose: The purpose of this request is to make changes to select OPTN membership forms to maintain current and effective data collection. Potential improvements have been identified as both OPTN members and staff have utilized the applications. Verbiage can be clarified or improved, grammatical and typographical errors should be corrected, inadvertent exclusions must be rectified, and formatting may be adjusted. These updates would improve the application process for OPTN members and staff processing applications without increasing the burden.

This memo explains the non-substantive changes and provides a supporting rationale.

Changes: Table A 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 1-18. 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. The proposed changes in Attachments 1-18 are minor grammatical, organizational, or functional updates. Many of the updates, such as verbiage or section title name changes, are duplicated across multiple forms. These updates do not impose additional data or documentation submission from OPTN members.

All edits are intended to improve the application process for both OPTN members and staff and to collect data more efficiently without increasing burden.

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 29, 2024.

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

PROPOSED CLARIFICATIONS AND NON-SUBSTANTIVE CHANGES:

Table A

Instrument	Variable	Change implemented	Rationale
01_OPTN Membership Application for Transplant Hospitals and Programs	Page Hospital - 2	Question verbiage improved; changed the word “what” to “which”	Grammar improvement; Provides clarity for members completing the form
01_OPTN Membership Application for Transplant Hospitals and Programs	Page Hospital - 2	Response format updated from an attestation check box to a yes or no option “Is this a standalone pediatric hospital? Yes or No”	Improves responses; Provides staff with the information requested
01_OPTN Membership Application for Transplant Hospitals and Programs	Page Hospital - 6	Question 1 verbiage improved; Members asked to provide a “comprehensive summary” instead of an “executive summary”	Improves clarity regarding the required documentation; This line of instruction has proven to be unclear and confusing for members
03_OPTN Membership Application for Kidney Transplant Programs	Page Kidney - 4	“Donor Surgeon” options removed from table drop-down menu in the “Primary, Additional, or Other” column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice

Instrument	Variable	Change implemented	Rationale
03_OPTN Membership Application for Kidney Transplant Programs	Page Kidney – 9, 15	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members
03_OPTN Membership Application for Kidney Transplant Programs	Page Kidney - 33	Question verbiage clarified; Added the word “pediatric” to question 2	Verbiage clarified to specify key personnel pathways pertain to the pediatric component; Aligns verbiage with pediatric sections of other applications
03_OPTN Membership Application for Kidney Transplant Programs	Pages Kidney - 39,40	Formatting updated for each primary living kidney donor surgeon position; question 6 was revised to Part 8A and question 7 was revised to Part 8B; given the changes above question 8 was revised to question 6	Reorganization of information; No new questions added to form; Improves clarity regarding position requirements for members; Improves staff efficiency when processing applications; Improves organization for MPSC reviewers
04_OPTN Membership Application for Liver Transplant Programs	Page Liver - 4	“Donor Surgeon” options removed from table drop-down menu in the “Primary, Additional, or Other” column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice
04_OPTN Membership Application for Liver Transplant Programs	Page Liver – 10, 16	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members

Instrument	Variable	Change implemented	Rationale
04_OPTN Membership Application for Liver Transplant Programs	Page Liver - 30	Requirement verbiage corrected; Language incorrectly asked member to provide progress report documentation before conditional approval was granted instead of during the conditional approval period; Removed the words "Provide documentation that"	Aligns verbiage with other applications pertaining to conditional approval pathways; Clarifies progress reporting requirements
04_OPTN Membership Application for Liver Transplant Programs	Page Liver - 34	Question verbiage clarified; Added the word "pediatric" to question 2	Verbiage clarified to specify key personnel pathways pertain to the pediatric component; Aligns verbiage with pediatric sections of other applications
04_OPTN Membership Application for Liver Transplant Programs	Pages Liver - 39-44	Formatting updated for primary living donor liver surgeon positions and conditional approval; Questions reorganized to align with other applications; Question 1 moved to Part 9A, question 2 moved to Part 9B, question 6 moved to part 9C, and the previous questions 3-5 were revised to questions 1-3; Instructions regarding conditional approval clarified	Improves clarity regarding position requirements and instructions for members; Improves staff efficiency when processing applications; Improves organization for MPSC reviewers Clarifies instruction language for conditional approval option; No new questions added to form
05_OPTN Membership Application for Pancreas Transplant Programs	Page Pancreas - 4	"Donor Surgeon" options removed from table drop-down menu in the "Primary, Additional, or Other" column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice
05_OPTN Membership Application for Pancreas Transplant Programs	Page Pancreas – 9, 16	Question 2 verbiage improved; Updated word "or" to "and" and added "documentation of education" as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members

Instrument	Variable	Change implemented	Rationale
05_OPTN Membership Application for Pancreas Transplant Programs	Page Pancreas – 26, 27	Question verbiage clarified; Added the word “pediatric” to question 2	Verbiage clarified to specify key personnel pathways pertain to the pediatric component; Aligns verbiage with pediatric sections of other applications
06_OPTN Membership Application for Heart Transplant Programs	Page Heart - 4	“Donor Surgeon” options removed from table drop-down menu in the “Primary, Additional, or Other” column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice
06_OPTN Membership Application for Heart Transplant Programs	Page Heart – 9, 17	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members
06_OPTN Membership Application for Heart Transplant Programs	Page Heart - 24	Requirement verbiage corrected; Language incorrectly asked member to provide progress report documentation before conditional approval was granted instead of during the conditional approval period; Removed the words “Provide documentation that”	Aligns verbiage with other applications pertaining to conditional approval pathways; Clarifies progress reporting requirements
06_OPTN Membership Application for Heart Transplant Programs	Page Heart – 26, 27	Question verbiage clarified; Added the word “pediatric” to question 2 on page 26 and question 3 on page 27	Verbiage clarified to specify key personnel pathways pertain to the pediatric component; Aligns verbiage with pediatric sections of other applications
07_OPTN Membership Application for Lung Transplant Programs	Page Lung - 4	“Donor Surgeon” options removed from table drop-down menu in the “Primary, Additional, or Other” column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice

Instrument	Variable	Change implemented	Rationale
07_OPTN Membership Application for Lung Transplant Programs	Page Lung – 9, 19	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members
07_OPTN Membership Application for Lung Transplant Programs	Page Lung – 10, 30	Pathway title corrected; Removed the word “formal” within question 5 on page 10 and question 2 on page 30	Corrects typo; Aligns application verbiage with pathway title in bylaws
08_OPTN Membership Application for Islet Transplant Programs	Page Islet - 5	“Donor Surgeon” options removed from table drop-down menu in the “Primary, Additional, or Other” column; “Clinical Leader” added to the “Surgeon, Physician, or Clinical Leader” column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice
08_OPTN Membership Application for Islet Transplant Programs	Page Islet - 14	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members
09_OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	Page VCA – 9, 24	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members
09_OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	Page VCA - 18	Added question (question 2) to include uterus specific procurement option	Corrects error; Uterus specific procurement option inadvertently excluded in the previous change package; No increase in burden, as the general procurement requirement has always been applicable to primary VCA surgeons, this provides uterus surgeons an alternative way to fulfill procurement requirements.

Instrument	Variable	Change implemented	Rationale
09_OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	Page VCA – 26, 27	Formatting updated for primary living uterus donor surgeon position; Reorganization of information; No new questions added to form	Improves clarity regarding position requirements for members; Improves staff efficiency when processing applications; Improves organization for MPSC reviewers
10_OPTN Membership Application for Intestine Transplant Programs	Page Intestine - 4	“Donor Surgeon” options removed from table drop-down menu in the “Primary, Additional, or Other” column	Corrects error; This column is used for the assessment of program coverage/staffing levels, the checkboxes within the table are used to demonstrate living donor or pediatric component affiliation; Aligns form with application processing practice
10_OPTN Membership Application for Intestine Transplant Programs	Page Intestine – 9, 15	Question 2 verbiage improved; Updated word “or” to “and” and added “documentation of education” as an option to demonstrate proof of education rather than limiting applicant to a resume or CV	Broadens the acceptable forms of documentation utilized to demonstrate proof of education; Improves clarity as this line of instruction has proven to be unclear and confusing for members

Attachments:

1. 01_OPTN Membership Application for Transplant Hospitals and Programs REDLINE
2. 01_OPTN Membership Application for Transplant Hospitals and Programs CLEAN
3. 03_OPTN Membership Application for Kidney Transplant Programs REDLINE
4. 03_OPTN Membership Application for Kidney Transplant Programs CLEAN
5. 04_OPTN Membership Application for Liver Transplant Programs REDLINE
6. 04_OPTN Membership Application for Liver Transplant Programs CLEAN
7. 05_OPTN Membership Application for Pancreas Transplant Programs REDLINE
8. 05_OPTN Membership Application for Pancreas Transplant Programs CLEAN
9. 06_OPTN Membership Application for Heart Transplant Programs REDLINE
10. 06_OPTN Membership Application for Heart Transplant Programs CLEAN
11. 07_OPTN Membership Application for Lung Transplant Programs REDLINE
12. 07_OPTN Membership Application for Lung Transplant Programs CLEAN
13. 08_OPTN Membership Application for Islet Transplant Programs REDLINE
14. 08_OPTN Membership Application for Islet Transplant Programs CLEAN

15. 09_OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs REDLINE
16. 09_OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs CLEAN
17. 10_OPTN Membership Application for Intestine Transplant Programs REDLINE
18. 10_OPTN Membership Application for Intestine Transplant Programs CLEAN