DEPARTMENT OF HEALTH & HUMAN SERVICES



Rockville, MD 20857

DATE: June 2, 2021

TO: Josh Brammer, OMB Desk Officer

FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) Division of

Transplantation requests approval for non-substantive changes to the Organ Procurement and Transplantation Network (OPTN) Collection

(OMB 0915-0184 expiration date 08/31/2023).

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.

The OPTN Membership Applications underwent a significant overhaul to the design of the forms to better align with the OPTN Bylaws. As a result of this major revision effort, some grammatical, numbering errors, and inconsistencies with the embedded instructions were identified.

The United Network for Organ Sharing, the contractor for the OPTN, would like to rectify these non-substantive changes by using a change memo in 2021 in preparation for a complete packet revision of all OPTN

Membership forms in 2022.

Time Sensitivity: The OPTN data collection changes must be completed in a timely manner

so that work may begin on the complete packet revision of OPTN

Membership forms. Approval of these changes is requested by June 12,

2021.

Burden: The non-substantive changes included herein do not substantially change

the estimated reporting burden for current and prospective OPTN

members and may lead to reductions in the burden.

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.

OPTN Membership Application for Transplant Hospitals and Programs

a. Page 1, Title – Addition

Added "and Programs" to the title of form.

<u>Rationale</u>: Title Change. This form is used for new transplant hospitals and well as transplant programs within existing transplant hospitals.

b. Page 1-2, Signatures – Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

<u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility.

c. Page 4, Part 1: General Information - Change/Addition

Added "Transplant" and "(where transplants occur)" to request for Hospital Address. <u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

d. Page 5, Part 2: Designated Transplant Program Requirement - Change

Changed the spelling of the abbreviation of U.S. Department of Health and Human Services from "HSS" to "HHS."

Rationale: Spelling correction.

e. Page 7, Part 3: Facilities and Resources, Question 9 (Blood Bank Services) – Addition

Added an "s" to "blood bank."

Rationale: Grammar.

OPTN Membership Application for Kidney Transplant Programs

a. Page 1-2, Signatures - Change/Addition

Beyond OPTN representative, removed named positions from signature form. Replaced with blank spaces for potential signatures.

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<u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility.

b. Page 4, Part 1: General Information - Change/Addition

Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 4, Part 1: General Information – Removal

Removed checkboxes requesting applicant to indicate if form is being used for a pediatric or living donor component.

Rationale: Unnecessary to completion or processing of application form.

d. Page 5, Part 2: Program Director(s) - Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

e. Page 6, Part 3: Primary Program Administrator -Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Page 7, Part 4: Primary Data Coordinator -Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator. Rationale: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Pages 10, 12, 16, 19, 21, 24, 27, 30, 31, 39, 44, 47, 50, 55: Additional Page Breaks – Addition

Added page breaks at every pathway requirement throughout the form.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

h. Pages 10, 12, 16, 17, 19, 20, 21, 22, 24, 25, 27, 28, 30, 31, 36, 37, 39, 44, 45, 47, 48, 50, 51, 53, 55, 56, 58, 59: Clarification of Experience Log Requirements – Change/Addition

Replaced "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

i. Page 15, Part 6: Primary Kidney Transplant Physician Requirements, Question 5 – Change

Changed referenced pathways from 5A to 6A, 5B to 6B, 5C to 6C, 5D to 6D, 5E to 6E, and 5F to 6F respectively.

Rationale: Numbering error.

j. Page 16, Part 6: Primary Kidney Transplant Physician Requirements, Part 6A – Change

Changed title of Transplant Nephrology Fellowship Pathway from 5A to 6A.

Rationale: Numbering error.

k. Page 19, Part 6: Primary Kidney Transplant Physician Requirements, Part 6B – Change

Changed title of Clinical Experience Pathway from 5B to 6B.

Rationale: Numbering error.

Page 21, Part 6: Primary Kidney Transplant Physician Requirements, Part 6C – Change

Changed title of Three-year Pediatric Nephrology Fellowship Pathway from 5C to 6C. Rationale: Numbering error.

m. Page 24, Part 6: Primary Kidney Transplant Physician Requirements, Part 6D – Change

Changed title of Twelve-month Pediatric Transplant Nephrology Fellowship Pathway from 5D to 6D.

Rationale: Numbering error.

n. Page 27, Part 6: Primary Kidney Transplant Physician Requirements, Part 6E – Change

Changed title of Combined Pediatric Nephrology Training and Experience Pathway from 5E to 6E.

Rationale: Numbering error.

o. Page 27, Part 6: Primary Kidney Transplant Physician Requirements, Part 6E, Question 2 –Removal

Removed "This experience must be documented on the log provided."

<u>Rationale</u>: There is no log requirement specifically with this question. The "minimum of 2 years of experience" will be ascertained within the log for this pathway.

p. Page 30, Part 6: Primary Kidney Transplant Physician Requirements, Part 6F – Change

Changed title of Conditional Approval for Primary Transplant Physician from 5F to 6F. Rationale: Numbering error.

q. Page 35, Part 7A: Primary Pediatric Kidney Transplant Surgeon Requirements, Question 6: Pediatric-Specific Requirements – Change

Moved question "Pediatric-Specific Requirements" to precede pathway subsections. Rationale: Move of question. Ouestion was getting lost behind the pathway subsections.

r. Page 38, Part 7A: Primary Pediatric Kidney Transplant Surgeon Requirements, Section 5A, Question 4—Change

Changed numbering from "5" to "4."

Rationale: Numbering error.

s. Page 42, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements, Question 3b: Certification –Addition

Added "This option can only be utilized if pursuing the Three-year Pediatric Nephrology Fellowship Pathway."

Rationale: Clarification of requirements to follow the OPTN Bylaws.

t. Page 43, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements, Question 5 – Change

Changed referenced pathways from 5A to 6A, 5B to 6B, and 5C to 6C respectively. Rationale: Numbering error.

Page 44, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements, Part 6A – Change

Changed title of Three-year Pediatric Nephrology Fellowship Pathway from 5A to 6A. Rationale: Numbering error.

Page 47, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements, Part 6B – Change

Changed title of Twelve-month Pediatric Transplant Nephrology Fellowship Pathway from 5B to 6B.

Rationale: Numbering error.

w. Page 50, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements, Part 6C –Change

Changed title of Combined Pediatric Nephrology Training and Experience Pathway from 5C to 6C.

Rationale: Numbering error.

x. Page 50, Part 7B: Primary Pediatric Kidney Transplant Physician Requirements, Part 6C, Question 2 –Removal

Removed "This experience must be documented on the log provided."

<u>Rationale</u>: There is no log requirement specifically with this question. The "minimum of 2 years of experience" will be ascertained within the log for this pathway.

y. Page 53, Part 7C: Conditional Approval for a Pediatric Component, Questions 1 and 2 – Addition

Added two questions to identify "Name of Proposed Primary Pediatric Kidney Transplant Surgeon or Physician who fully meets the bylaw requirements" (Question 1) and "Name of Proposed Primary Pediatric Kidney Transplant Surgeon or Physician who is being proposed as conditional personnel" (Question 2).

<u>Rationale</u>: A requirement of the conditional pathway for a pediatric component is that one of the primary surgeons or physicians needs to be fully approved. Adding these individuals up front adds no additional burden and makes it easier to process the application.

z. Page 53, Part 7C: Conditional Approval for a Pediatric Component, Option A – Change

Changed referenced section for Primary Pediatric Kidney Transplant Physician Requirements from Part 5C to 7B. Changed referenced section for Primary Kidney Transplant Physician Requirements from Part 3 to 5, the Formal 2-year transplant fellowship pathway from Part 3 to 5, Section 5A, and the Clinical Experience Pathway from Part 3 to 5, Section 5B.

Rationale: Numbering error.

aa. Page 55, Part 7C: Conditional Approval for a Pediatric Component, Option B – Change

Changed referenced section for Primary Pediatric Kidney Transplant Surgeon Requirements from 5B to 7A.

Rationale: Numbering error.

bb. Page 56, Part 7C: Conditional Approval for a Pediatric Component, Option B – Change

Changed phrasing from "has" to "should have."

<u>Rationale</u>: Clarification of requirement. The physician does not have to observe at least 3 organ procurements and at least 3 pediatric kidney transplants in order to be approved conditionally.

cc. Page 58, Part 8: Kidney Transplant Programs that Perform Living Donor Recovery, Question 6 – Change

Changed "Provide this surgeon's resume/CV with the application" to "Provide this surgeon's completion of an approved fellowship in kidney."

<u>Rationale</u>: Clarification of requirement. Matches the requirement to have completion of fellowship better than a copy of the resume/CV would show.

dd. Page 59, Part 8: Kidney Transplant Programs that Perform Living Donor Recovery, Question 7 – Removal

Removed "Provide the letter with the application"

Rationale: Redundant. This question already asks for the letter.

OPTN Membership Application for Liver Transplant Programs

a. Page 1-2, Signatures – Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

<u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility.

b. Page 4, Part 1: General Information – Change/Addition

Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 4, Part 1: General Information – Removal

Removed checkboxes requesting applicant to indicate if form is being used for a pediatric or living donor component.

Rationale: Unnecessary to completion or processing of application form.

d. Page 5, Part 2: Program Director(s) - Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

e. Page 6, Part 3: Primary Program Administrator – Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Page 7, Part 4: Primary Data Coordinator – Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator. Rationale: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Pages 10, 12, 16, 18, 20, 23, 26, 29, 36, 38, 43, 46, 49, 56: Additional Page Breaks – Addition

Added page breaks at every pathway requirement throughout the form.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

h. Pages 10, 12, 16, 17, 18, 19, 20, 21, 24, 26, 27, 29, 30, 35, 36, 38, 43, 46, 47, 49, 50, 52, 53, 56, 58, 59: Clarification of Experience Log Requirements – Change/Addition Replaced "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

i. Pages 20 and 21, Part 6: Primary Liver Transplant Physician Requirements, Part 5C – Change

Corrected numbering sequence for section.

Rationale: Numbering error.

j. Page 34-35, Part 8A: Primary Pediatric Liver Transplant Surgeon Requirements, Question 6: Pediatric-Specific Requirements –Change

Moved question "Pediatric-Specific Requirements" to precede pathway subsections.

<u>Rationale</u>: Needed to move the question as it was getting lost behind the pathway subsections.

k. Page 41, Part 8B: Primary Pediatric Liver Transplant Physician Requirements, Question 3: Certification – Removal

Removed option to select 3b if the proposed physician is without certification. As this removal now created only one option to proceed, removed '3a' from Certification question and the direction to "Check one and provide corresponding documentation." Added a checkbox, which follows the format of Question 2 above.

Rationale: The option marked '3b' does not exist for proposed primary pediatric liver physician.

l. Page 52, Part 8C: Conditional Approval for a Pediatric Component, Questions 1 and 2 –Addition

Added two questions to identify "Name of Proposed Primary Pediatric Liver Transplant Surgeon or Physician who fully meets the bylaw requirements" (Question 1) and "Name of Proposed Primary Pediatric Liver Transplant Surgeon or Physician who is being proposed as conditional personnel" (Question 2).

<u>Rationale</u>: A requirement of the conditional pathway for a pediatric component is that either the primary surgeon or physician needs to be fully approved. Adding these individuals up front adds no additional burden and makes it easier to process the application.

m. Page 56, Part 9: Liver Transplant Programs that Perform Living Donor Recovery, Question 1: Living Donor Surgeon – Removal

Removed two lines for additional proposed Living Donor Surgeons.

<u>Rationale</u>: The OPTN Bylaws only require a living donor component have two living donor surgeons. Reducing these lines to match the bylaws and reduce confusion.

n. Page 56, Part 9: Liver Transplant Programs that Perform Living Donor Recovery, Question 2: Independent Living Donor Advocate (ILDA) – Change

Changed "kidney" to "liver"

<u>Rationale</u>: Clarification of Requirement. Requesting the ILDA affiliated with the living liver component.

OPTN Membership Application for Intestine Transplant Programs

a. Page 1-2, Signatures – Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

b. <u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility. **Page 5, Part 1: General Information – Change/Addition**

Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 6, Part 2: Program Director(s) - Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

d. Page 7, Part 3: Primary Program Administrator – Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

e. Page 8, Part 4: Primary Data Coordinator – Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator.

<u>Rationale</u>: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Pages 11, 13, 17, 19: Additional Page Breaks - Addition

Added page breaks at every pathway requirement throughout the form.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

g. Pages 11, 13, 17, 19: Clarification of Experience Log Requirements – Change/Addition

Removed "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

OPTN Membership Application for Pancreas Transplant Programs

a. Page 1-2, Signatures - Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

b. <u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility. **Page 4, Part 1: General Information – Change/Addition**

Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 4, Part 1: General Information – Removal

Removed checkbox requesting applicant to indicate if form is being used for a pediatric component.

Rationale: Unnecessary to completion or processing of application form.

d. Page 5, Part 2: Program Director(s) – Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

e. Page 6, Part 3: Primary Program Administrator – Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Page 7, Part 4: Primary Data Coordinator -Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator.

<u>Rationale</u>: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Pages 10, 12, 14, 18, 20, 22, 24, 29, 31, 33, 37, 39, 41, 43, : Additional Page Breaks – Addition

Added page breaks at every pathway requirement throughout the form.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

h. Pages 10, 12, 14, 18, 19, 20, 21, 24, 25, 29, 31, 33, 37, 38, 39, 40, 41, 43, 44:

Clarification of Experience Log Requirements - Change/Addition

Replaced "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

i. Page 16, Part 6: Primary Pancreas Transplant Physician Requirements, Question 3b – Change

Changed "surgeon" to "physician."

<u>Rationale</u>: Reword a question so that it is more understandable. This section applies to physicians, not surgeons

j. Page 35, Part 7B: Primary Pediatric Pancreas Transplant Physician Requirements, Question 3b – Change

Changed "surgeon" to "physician."

<u>Rationale</u>: Reword a question so that it is more understandable. This section applies to physicians, not surgeons.

OPTN Membership Application for Islet Transplant Programs

a. Pages 1-11, Page Numbers – Change

Removed the old version date and "Pancreas" and "Cell" from the footer.

<u>Rationale</u>: The page numbers listed featured the old version date and referred to the page numbers as "Pancreas Islet Cell."

b. Page 1-2, Signatures - Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

c. <u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility. Page 3, Part 1: General Information – Change/Addition

Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

d. Page 4, Part 2: Program Director(s) - Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

e. Page 5, Part 3: Primary Program Administrator – Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Page 6, Part 4: Primary Data Coordinator – Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator. Rationale: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Page 7, Part 5: Islet Transplant Program Clinical Leader Requirements, Questions 3 and 5 – Change

Replaced "This experience must be documented on the log provided" with "This experience must be documented on a log."

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

h. Page 10, Part 6: Islet Transplant Program Additional Requirements – Removal Removed the second use of the word "are" from "Are islet cells are isolated and processed at a location other than the transplant facility?" Rationale: Grammar correction.

OPTN Membership Application for Heart Transplant Programs

a. Page 1-2, Signatures - Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

b. <u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility. Page 4, Part 1: General Information – Change/Addition Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 4, Part 1: General Information – Removal

Removed checkboxes requesting applicant to indicate if form is being used for a pediatric component.

Rationale: Unnecessary to completion or processing of application form.

d. Page 5, Part 2: Program Director(s) - Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

e. Page 6, Part 3: Primary Program Administrator – Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Page 7, Part 4: Primary Data Coordinator -Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator. Rationale: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Pages 10, 12, 14, 18, 20, 22, 28, 30, 32, 38, 40, 42: Additional Page Breaks –Addition

Added page breaks at every pathway requirement throughout the form.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

h. Pages 10, 12, 14, 18, 19, 20, 22, 23, 28, 30, 32, 36, 38, 40, 42, 43, 46: Clarification of Experience Log Requirements – Change/Addition

Replaced "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

 i. Page 12, Part 5: Primary Heart Transplant Surgeon Requirements, Part 5B – Change

Changed title of Twelve-month Heart transplant Fellowship Pathway from 4B to 5B. Rationale: Numbering error.

 j. Page 14, Part 5: Primary Heart Transplant Surgeon Requirements, Part 6B – Change

Changed title of Clinical Experience Pathway from 4C to 5C.

Rationale: Numbering error.

k. Page 17, Part 6: Primary Heart Transplant Physician Requirements, Question 5 – Change

Changed referenced pathways from 5A to 6A, 5B to 6B, and 5C to 6C respectively. Rationale: Numbering error.

 Page 18, Part 6: Primary Heart Transplant Physician Requirements, Part 6A – Change

Changed title of Twelve-month Transplant Cardiology Fellowship Pathway from 5A to 6A.

Rationale: Numbering error.

m. Page 20, Part 6: Primary Heart Transplant Physician Requirements, Part 6B – Change

Changed title of Clinical Experience Pathway from 5B to 6B.

Rationale: Numbering error.

n. Page 22, Part 6: Primary Heart Transplant Physician Requirements, Part 6C – Change

Changed title of Conditional Approval for Primary Transplant Physician from 5C to 6C. Rationale: Numbering error.

o. Page 27, Part 7A: Primary Pediatric Heart Transplant Surgeon Requirements, Question 6: Pediatric-Specific Requirements –Change

Moved question "Pediatric-Specific Requirements" to precede pathway subsections. Rationale: Moved question. It was getting lost behind the pathway subsections.

p. Page 34, Part 7B: Primary Pediatric Heart Transplant Physician Requirements, Question 1 –Addition

Added "Pediatric" to Name of Proposed Primary Heart Transplant Physician. Rationale: Rewording a question so it is more understandable.

q. Page 35, Part 3B: Certification. Check one and provide corresponding documentation- Removal

r. Removed option to select 3b if the proposed physician is without certification. As this removal now created only one option to proceed, removed '3a' from Certification question and the direction to "Check one and provide corresponding documentation." Added a checkbox, which follows the format of Question 2 above.

s. Page 36, Part 7B: Primary Pediatric Heart Transplant Physician Requirements, Question 5 –Change

Changed referenced pathways from 5A to 6A, 5B to 6B, and 5C to 6C respectively. Rationale: Numbering error.

t. Page 38, Part 7B: Primary Pediatric Heart Transplant Physician Requirements, Part 6A –Change

Changed title of Twelve-month Transplant Cardiology Fellowship Pathway from 5A to 6A.

Rationale: Numbering error.

u. Page 40, Part 7B: Primary Pediatric Heart Transplant Physician Requirements, Part 6B –Change

Changed title of Clinical Experience Pathway from 5B to 6B.

Rationale: Numbering error.

v. Page 42, Part 7B: Primary Pediatric Heart Transplant Physician Requirements, Part 6C –Change

Changed title of Conditional Approval for Primary Transplant Physician from 5C to 6C. Rationale: Numbering error.

w. Page 45, Part 7C: Conditional Approval for a Pediatric Component, Questions 1 and 2 – Addition

Added two questions to identify "Name of Proposed Primary Pediatric Heart Transplant Surgeon or Physician who fully meets the bylaw requirements" (Question 1) and "Name of Proposed Primary Pediatric Heart Transplant Surgeon or Physician who is being proposed as conditional personnel" (Question 2).

<u>Rationale</u>: A requirement of the conditional pathway for a pediatric component is that one of the primary surgeons or physicians needs to be fully approved. Adding these individuals up front adds no additional burden and makes it easier to process the application.

OPTN Membership Application for Lung Transplant Programs

a. Page 1-2, Signatures - Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

b. <u>Rationale</u>: Required signatories depend upon what portions of the form are being competed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility. Page 4, Part 1: General Information – Change/Addition Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 4, Part 1: General Information – Removal

Removed checkboxes requesting applicant to indicate if form is being used for a pediatric component.

Rationale: Unnecessary to completion or processing of application form

d. Page 5, Part 2: Program Director(s) –Addition

Added "new" to request to include resume/CV of each individual listed.

Rationale: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

e. Page 6, Part 3: Primary Program Administrator -Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

f. Page 7, Part 4: Primary Data Coordinator -Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator. Rationale: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Pages 10, 12, 14, 16, 20, 22, 24, 26, 31, 33, 35, 37, 40, 41, 43, 45, 47: Additional Page Breaks –Addition

Added page breaks at every pathway requirement throughout the form. Rationale: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

h. Pages 10, 12, 14, 16, 20, 22, 23, 24, 26, 27, 31, 33, 35, 37, 41, , 43, 44, 45, 47, 48: Clarification of Experience Log Requirements – Change/Addition

Replaced "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

i. Pages 22 and 23, Part 6: Primary Lung Transplant Physician Requirements, Part 5B – Change

Corrected numbering sequence for section.

Rationale: Numbering error.

j. Page 31, Part 7A: Primary Pediatric Lung Transplant Surgeon Requirements, Part 5A – Change

Corrected numbering sequence for section.

Rationale: Numbering error.

k. Page 35, Part 7A: Primary Pediatric Lung Transplant Surgeon Requirements, Part 5C – Change

Corrected numbering sequence for section.

Rationale: Numbering error.

I. Pages 41 and 42, Part 7B: Primary Pediatric Lung Transplant Physician Requirements, Part 5A – Change

Corrected numbering sequence for section.

Rationale: Numbering error.

m. Pages 43 and 44, Part 7B: Primary Pediatric Lung Transplant Physician Requirements, Part 5B – Change

Corrected numbering sequence for section.

Rationale: Numbering error.

n. Pages 47 and 48, Part 7B: Primary Pediatric Lung Transplant Physician Requirements, Part 5D –Change

Corrected numbering sequence for section.

Rationale: Numbering error.

OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs

a. Page 1-2, Signatures – Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

<u>Rationale</u>: Required signatories depend upon what portions of the form are being completed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility.

b. Page 5, Part 1: General Information – Change/Addition

Changed "Program Office" to "Hospital" and added "(where transplants occur)" to request for Hospital Address.

<u>Rationale</u>: This is to make clear the address that is being requested is the location at the hospital where transplants take place.

c. Page 5, Part 1: General Information – Removal

Removed "(s)" from "Indicate which VCA program(s) the hospital is applying for OPTN Membership.

<u>Rationale</u>: This form should not be used to apply for more than one VCA program as it cannot fully support the request if different primary surgeons and physicians are being proposed per the VCA category.

d. Page 5, Part 1: General Information- Addition

Added, "This form should be only used to apply for one VCA program at the time". Rationale: This form should not be used to apply for more than one VCA program as it cannot fully support the request if different primary surgeons and physicians are being proposed per the VCA category.

e. Page 6, Part 2: Program Director(s) - Addition

Added "new" to request to include resume/CV of each individual listed.

<u>Rationale</u>: If the transplant program director has already been identified in a previous request, we do not ask for the program to resubmit a resume or CV.

f. Page 7, Part 3: Primary Program Administrator – Addition

Added "Complete the section only if you are updating the Primary Program Administrator position for the program" to request to identify the Primary Program Administrator.

<u>Rationale</u>: If the primary program administrator has already been identified in a previous request, we do not ask for the program to resubmit this information.

g. Page 8, Part 4: Primary Data Coordinator – Addition

Added "Complete the section only if you are updating the Primary Data Coordinator position for the program" to request to identify the Primary Data Coordinator. Rationale: If the primary data coordinator has already been identified in a previous request, we do not ask for the program to resubmit this information.

h. Pages 10, 13, 16, 17: Additional Page Breaks – Addition

Added page breaks at every pathway requirement throughout the form.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

i. Pages 9, 13, 15, 16, 18: Clarification of Experience Log Requirements – Change/Addition

Replaced "This experience must be documented on the log provided" with the corresponding log requirements taken from the OPTN Bylaws.

<u>Rationale</u>: We do not require that applicants use the log template (OPTN Membership Surgeon or Physician Log). We will accept their submission as long as it meets the requirements outlined in the OPTN Bylaws.

j. Page 11, Part 5: Primary VCA Transplant Surgeon Requirements, Part 4A, Question 2 – Change

Changed "Accreditation from" to "Completion of an" Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery. Removed "a copy of ACGME accreditation" and replaced it with "proof of completion of the fellowship."

<u>Rationale</u>: Clarification of requirement. The proof of completion of the fellowship is the requirement, not the ACGME accreditation of the fellowship program itself.

k. Page 14, Part 5: Primary VCA Transplant Surgeon Requirements, Part 4B, Question 2 – Change

Removed "a copy of ACGME accreditation" and replaced it with "proof of completion of the fellowship."

<u>Rationale</u>: Clarification of requirement. The proof of completion of the fellowship is the requirement, not the ACGME accreditation of the fellowship program itself.

Page 17, Part 5: Primary VCA Transplant Surgeon Requirements, Part 4D, Question 2 – Change

Removed "must" from "Does this type of VCA transplant for which the surgeon is applying meet all nine of the following criteria?"

Rationale: Grammar

m. Page 18, Part 5: Primary VCA Transplant Surgeon Requirements, Part 4D,Question 7 – Change

Changed "1 through 5" to "1 through 6"

Rationale: Clarification of requirement. Numbering error.

OPTN Membership Application for Histocompatibility Laboratories

a. Page 1-2, Signatures – Change/Addition

Beyond OPTN representative, removed named positions required to sign form. Replaced with blank spaces for signature.

b. <u>Rationale</u>: Required signatories depend upon what portions of the form are being competed. The OPTN representative will always have to sign, but it varies among the other positions. Blanking out the signatures lines while still having a space to sign adds flexibility. **Page 3, Part 1: General Information – Change**

Replaced "OPO" with "Lab" in the request for a website address.

Rationale: Clarification of Requirement. Seeking the lab's website address.

c. Page 3, Part 1: General Information – Change

Replaced "Program" with "Laboratory" Coverage Plan when indicating the portion of the application to be completed.

<u>Rationale</u>: Clarification of Requirement. Key personnel changes must include the completion of Part 5 of the application.

d. Page 6, Part 3: Facilities and Resources, Question 3 – Change

Replaced "transplant program" with "OPO" in the request for a written agreement for OPO affiliation.

<u>Rationale</u>: Clarification of Requirement. Seeking written agreements for each OPO the laboratory serves.

e. Pages 8, 10, 11, 12, 13: Additional Page Breaks – Addition

Added page breaks at key personnel requirements within Part 4.

<u>Rationale</u>: This allows those who are processing the application forms to more easily segment the document to prepare for confidential medical peer review.

f. Page 9, Part 4: Histocompatibility Laboratory Key Personnel, Question 1 – Removal

Removed the "1" next to "If the proposed individual is a professional being considered for the position of the histocompatibility laboratory director, and has not served in the role of laboratory director prior to the date of application, all of the following must be provided."

Rationale: Numbering error. This portion is all part of "Pathway 2."

OPTN Membership Application Surgeon or Physician Log

a. Page 1: Surgeon Log - Change

Replaced "FX" with "Fellowship"

Rationale: Formatting. Clarification of requirement by spelling out an abbreviation.

b. Page 1: Surgeon Log - Addition

Added Signature Line.

Rationale: Formatting. Allows a signature to be captured on this log page if needed.

c. Page 1: Surgeon Log - Change

Replaced "FX" with "Fellowship"

Rationale: Formatting. Clarification of requirement by spelling out an abbreviation.

d. Page 2: Physician Log - Addition

Added Signature Line.

Rationale: Formatting. Allows a signature to be captured on this log page if needed.

e. Page 2: Physician Log - Removal

Removed header "Components that perform transplants in recipients less than 18 years old", as well as sub headers for "Liver" and "Heart."

<u>Rationale</u>: Formatting. This section can be used for all pediatric components, not just the liver and heart.

Attachments:

- 1. OPTN Membership Application for Transplant Hospitals and Programs REDLINE
- 2. OPTN Membership Application for Transplant Hospitals and Programs CLEAN
- 3. OPTN Membership Application for Kidney Programs REDLINE
- 4. OPTN Membership Application for Kidney Programs CLEAN
- 5. OPTN Membership Application for Liver Programs REDLINE
- OPTN Membership Application for Liver Programs CLEAN
- 7. OPTN Membership Application for Intestine Programs REDLINE
- 8. OPTN Membership Application for Intestine Programs CLEAN
- 9. OPTN Membership Application for Pancreas Programs REDLINE
- 10. OPTN Membership Application for Pancreas Programs CLEAN
- 11. OPTN Membership Application for Islet Programs REDLINE
- 12. OPTN Membership Application for Islet Programs CLEAN
- 13. OPTN Membership Application for Heart Programs REDLINE
- 14. OPTN Membership Application for Heart Programs CLEAN
- 15. OPTN Membership Application for Lung Programs REDLINE
- 16. OPTN Membership Application for Lung Programs CLEAN
- 17. OPTN Membership Application for VCA Transplant Programs REDLINE
- 18. OPTN Membership Application for VCA Transplant Programs CLEAN
- 19. OPTN Membership Application for Histocompatibility Laboratories REDLINE
- 20. OPTN Membership Application for Histocompatibility Laboratories CLEAN
- 21. OPTN Membership Application Surgeon or Physician Log REDLINE
- 22. OPTN Membership Application Surgeon or Physician Log CLEAN