

## **IMPORTANT POLICY NOTICE**

**To:** Transplant Professionals

**From:** James B. Alcorn  
Director, Policy

**RE:** Changes to OPTN Bylaws and Policies from actions at December 2015 Board of Directors Meeting

**Date:** December 23, 2015

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The attached report summarizes changes to the OPTN Policies and Bylaws approved by the OPTN/UNOS Board of Directors at its December 2015 meeting. This policy notice provides the specific Policy and Bylaws language changes and the corresponding implementation dates.

When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the approved changes reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at <http://optn.transplant.hrsa.gov/governance/policy-notices/>.

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws, has also been updated to reflect the changes resulting from the meeting. It can also be found at <http://optn.transplant.hrsa.gov/governance/compliance/optn-evaluation-plan/>.

Thank you for your careful review of this policy notice. If you have any questions about a particular Board of Directors' action, please contact your regional administrator at (804) 782-4800.

# ***Proposal to Revise OPTN Data Release Policies***

**Sponsoring Committee: Data Advisory**

**Policy/Bylaws Affected: Policies 19: Data Release, 19.1: Mailing Lists, 19.2: Composite Demographic Data, 19.3: Organ Center Data; 19.4: Sharing Arrangements, 19.5: Members, 19.6: Public Release of Transplant Hospital and OPO Activity, 19.7: Release of Transplant Hospital Specific Data, 19.8: Review of Member Specific Data, 19.9: Access to Recipient Outcomes Data, 19.10: Information before the Board of Directors, 19.11: Release of Human Leukocyte Antigen (HLA) Type of a Recipient’s Prior Donor, 19.12: Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier, 19.13: Access to Database, 19.14: Transfer of Information, 19.15: Specific Projects, 19.16: Public Use, Presentations, and Publications, and 19.17: Committee Access to Data**

**Public Comment: August 14, 2015 – October 14, 2015**

**Effective Date: March 1, 2016**

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## **Problem Statement**

Current OPTN policy restricts the release of organ procurement organization (OPO) and transplant hospital-identified data. The OPTN Final Rule (the Final Rule) requires the OPTN to release data in these instances:

- In response to “reasonable requests from the public for data needed for bona fide research or analysis purposes”
- In response to “reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”

The Health Resources and Services Administration (HRSA) clarified that this portion of the Final Rule applies to release of data identified by transplant hospital or OPO, which makes current OPTN policy inconsistent with the Final Rule.

## **Summary of Changes**

The revised policy confirms that the OPTN will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The remainder of the data release process will be maintained in standard operating procedures that will be available to the public.

## **What Members Need to Do**

Members will not need to do anything to comply with this policy. Both members and the public will have access to more OPTN data. The process for requesting institution-identified OPTN data will be publicly available in the Standard Operating Procedures for Review of OPTN Data Requests.

## Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

### **Policy 19: Data Release**

The OPTN Contractor will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS).

#### ~~19.1 Mailing Lists~~

~~Lists showing members' or program directors' names with addresses or telephone numbers may be released, only if both of the following requirements are met:~~

- ~~1. The Executive Director deems the request to be for a legitimate, non-commercial purpose furthering the objectives of the OPTN.~~
- ~~2. The OPTN Contractor receives an executed agreement restricting the use of the information for the permitted purpose.~~

#### ~~19.2 Composite Demographic Data~~

~~The OPTN Contractor may release to the public any composite demographic national, regional, or state data that is provided to HRSA through the OPTN Contract, such as the following:~~

- ~~• The number of transplant recipients, according to organ type, ethnicity, blood type, gender, and age~~
- ~~• The number of candidates on the Waiting List according to organ type, ethnicity, blood type, gender, and age~~
- ~~• The number and outcome of organs recovered~~

#### ~~19.3 Organ Center Data~~

~~The OPTN Contractor may release to the public composite Organ Center information such as the following:~~

- ~~• The number of organs allocated through the Organ Center~~
- ~~• Data reflecting Organ Center activity~~
- ~~• The number and final destination of kidneys placed internationally through the Organ Center~~

#### ~~19.4 Sharing Arrangements~~

~~The OPTN Contractor may release to the public the names of members participating in sharing arrangements approved by the Board of Directors.~~

#### ~~19.5 Members~~

~~The OPTN Contractor may release to the public listings of members (including names of personnel).~~

#### ~~19.6 Public Release of Transplant Hospital and OPO Activity~~

~~The OPTN Contractor may release to the public, without obtaining permission from each member, the analysis results containing the following data:~~

1. Updated transplant hospital-specific waiting list activity, by organ type, including but not limited to the number of candidates on the waiting list at the initiation of a period; the number of candidates added to the list; and the number of candidates removed from the list for death, transplant, and other reasons and, to the extent relevant to the organ type, the probability of survival on the waiting list within a specific period of time stratified by demographic and medical factors as determined appropriate by the Policy Oversight Committee (POC). These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.
2. Updated transplant hospital-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the POC.
3. Updated transplant hospital-specific or OPO-specific waiting time information, by organ type, stratified by demographic and medical variables as determined appropriate by the POC, and the probability of receiving a transplant within a specific period of time stratified by demographic and medical factors as determined appropriate by the POC.
4. Updated transplant hospital-specific risk adjusted survival rate information, along with percentage of transplants with follow up information, using data that may be validated by the member through the OPTN Contractor, by organ type, assessing transplants performed during a period that allows the OPTN Contractor sufficient time to collect the data and compute the rates as determined by the POC. The adjusted, transplant hospital-specific survival rate information may include, to the extent relevant to the organ type, the probability of survival pre-transplant, post-transplant and the probability of survival with or without a transplant. An appropriate period of analysis also will be determined by the POC.
5. Updated transplant hospital-validated transplant volumes as may be validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors as determined appropriate by the POC. These data may be presented on a calendar year basis and for such portions of the calendar year as determined by the POC. At a minimum, the OPTN Contractor may release the following transplant hospital volume information:
  - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients of a particular age.
  - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients with a particular diagnosis.
  - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
  - Transplant hospital-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor.
  - Transplant hospital-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
  - Transplant hospital-specific waiting list size on any given day, by organ type, according to the waiting list.
  - OPO-specific data on the number of non-U.S. citizen organ donors, by year and by organ type, using data that may be validated by the members through the OPTN Contractor.
  - Transplant hospital- and OPO-specific data submission compliance rates.
  - Updated OPO-specific donor procurement volumes, using data validated by the member through the OPTN Contractor, including organ-specific authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, using data validated by the member through the OPTN Contractor, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.
  - Updated OPO-specific organ transplant volume, using data validated by the member through the OPTN Contractor, showing number of organs procured, number of organs imported into the OPO, and number of organs exported from the OPO. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.

- ~~OPO specific organ transplant volume and size of waiting list, using data validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.~~
- ~~Transplant hospital, OPO, or other organization specific data as approved by the Executive Committee, which the OPTN anticipates will be otherwise duly released by the Department of Health and Human Services (HHS) to the public, together with such explanatory or other text or material as the Executive Committee deems appropriate to assist readers in understanding the data.~~

## **~~19.7 Release of Transplant Hospital Specific Data~~**

~~The OPTN Contractor may release to OPO members such transplant hospital specific data as are required for the OPOs to prepare reports or other documents required by the OPTN for the purposes of assessing the impact of variances, alternative local units and sharing agreements on organ allocation.~~

## **~~19.8 Review of Member Specific Data~~**

~~During the data validation process, the OPTN Contractor may release to members for their review such primary data as may be needed for member specific reports for public release. For example, donor and histocompatibility data about transplants performed at a transplant hospital may be sent to that transplant hospital for review (but not for modification without instruction to the OPTN Contractor by the original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to the OPTN Contractor by transplant hospitals. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions.~~

## **~~19.9 Access to Recipient Outcomes Data~~**

~~OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness of deceased donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the OPTN Contractor. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions. These data fields are located on the *Transplant Recipient Registration* forms and include all of the following:~~

### *Recipient status (all organs)*

- ~~Living — date of hospital report~~
- ~~Dead — date and cause of death~~
- ~~Re-transplanted prior to hospital discharge — date~~
- ~~Cause of retransplant (thoracic only)~~

### *Clinical information at discharge (kidneys only)*

- ~~Most recent serum creatinine prior to discharge~~
- ~~Did kidney produce >40 mL of urine in first 24 hours?~~
- ~~Did recipient need dialysis within first week?~~
- ~~Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?~~

### *Transplanted kidney, liver or pancreas status at discharge*

- ~~Functioning or failed~~
- ~~If failed, date and cause~~

- ~~Preservation Information (all organs)~~

## ~~19.10 Information Brought before the Board of Directors~~

~~The OPTN Contractor may release to the public any information brought before the Board of Directors in public sessions.~~

## ~~19.11 Release of Human Leukocyte Antigen (HLA) Type of a Recipient's Prior Donor~~

~~The OPTN Contractor may release a recipient's prior donor's HLA type to a transplant hospital if the recipient is under that transplant hospital's care, or to the laboratory that provides services to that transplant hospital, without obtaining permission from the transplant hospital that performed the original transplant or the laboratory that performed the donor's typing.~~

## ~~19.12 Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier~~

~~The OPTN Contractor may release, without obtaining permission from each member laboratory, the HLA type of deceased donors and recipients with the name and identifier of the laboratory that performed the typing to member laboratories for the purpose of resolving discrepant donor and recipient HLA typing results as set out in *Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results*.~~

## ~~19.13 Access to Database~~

~~Only OPTN Contractor staff, or individuals engaged by or adjunct to Contractor staff who are bound by contracts that prohibit competing interests and breaches of confidentiality, will be permitted to program or have direct access to data within the OPTN computer match program, or waiting list, or maintained in any other form. Members requesting access to data regarding their own candidates and recipients will be provided access to that information when practicable as determined by the OPTN Project Director. Unless permitted elsewhere in policy, neither individuals nor members will be given access to individual candidate, recipient, or member-specific information other than that from their own organization, without prior written approval from those individuals or members identified. Candidate, recipient, and institution-identified data will be made available to the Scientific Registry for Transplant Recipients (SRTR) Contractor.~~

## ~~19.14 Transfer of Information~~

~~All requests for data should be made through the Data Request System. Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to the additional requirements in *Policy 19.15: Specific Projects*.~~

~~Unless permitted by this Policy, data will be provided with the deletion of all candidate, recipient and transplant hospital specific identifying information. Comprehensive datasets with transplant hospital and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the POC.~~

~~Under some circumstances, transplant hospital-specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the POC using as guidance the Agreement for Release of Data, as approved by the POC. In order to~~

~~obtain these data, the submitting individual must meet the conditions for their release and sign an Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis.~~

~~Use of such data must meet the requirements of *Policy 19.16: Public Use, Presentations, and Publications*.~~

~~As required by the OPTN contract, the OPTN Contractor may release records which are identifiable as to candidate, recipient, transplant hospital or OPO without a signed Agreement for Release of Data only pursuant to official requests for data from the Department of Health and Human Services in accordance with federal or state laws and regulations.~~

## **~~19.15 Specific Projects~~**

~~Any individual or group requesting data requiring twenty or more hours of programming time and/or any statistical analysis of a specific question by the OPTN Contractor staff may be asked to submit a written concept paper to the POC. The POC (its chair plus representative committee members) will vote to approve or disapprove each request, and may also prioritize approved requests, based on scientific or clinical merit, importance to the OPTN, and the potential ability to address the question. The approval and priority status of each request will be provided to the submitting individual. Upon approval, the submitting individual will be notified of the OPTN Contractor staff assigned to complete the request. The submitting individual must indicate to the assigned staff whether he/she wishes to be directly involved in the analysis and the project work group.~~

~~Data will be provided with the deletion of all candidate and recipient specific identifying information. Transplant hospital identifiers may be provided to bona fide researchers who meet the conditions specified in Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided, as required by *Policy 19.16: Public Use, Presentations, and Publications*.~~

## **~~19.16 Public Use, Presentations, and Publications~~**

~~All scientific data provided and/or analyses performed by the OPTN Contractor utilizing data collected for the OPTN must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship.~~

### **~~19.16.A Public Use or Presentation of Specific Projects or Studies~~**

~~The scientific and analytical content of all abstracts or manuscripts developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the POC and any ad hoc work group appointed by that Committee prior to their public presentation or publication. If the analysis has not been provided prior to release by the investigator or institution, the OPTN Contractor cannot assume responsibility for the correctness of the findings or interpretations. Failure to include the OPTN Contractor in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or institution for additional data. Any contractor staff that makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. Contractor staff may not be listed as study authors without obtaining written permission from the appropriate staff. A copy of all published abstracts, manuscripts, or news releases should be submitted to staff and/or the POC for informational purposes as soon as practicable.~~

### **~~19.16.B Data Obtained Through the Data Request System~~**

~~Abstracts and manuscripts prepared using routinely available data obtained through the data request system do not require approval by the POC. Routinely available data will comprise all of the following:~~

- ~~1. Data provided in regularly updated standard reports~~
- ~~2. Data requested by OPTN members regarding their own institution or candidates and recipients~~
- ~~3. Data requested by the Department of Health and Human Services~~

~~However, the source and date of the data obtained must be acknowledged in text or graphic presentations. A copy of each published abstract, manuscript, or news release should be submitted to OPTN Contractor and/or the POC for informational purposes as soon as practicable. Publications that use data collected for the OPTN will include the following notice: *The data reported here have been supplied by [XXX], the OPTN Contractor. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official Policy or interpretation of the OPTN, or the U.S. Government.*~~

### **~~19.17 Committee Access to Data~~**

~~Confidential Information, as herein defined, will not be made available in a public meeting. In a non-public forum or meeting setting, access to Confidential Information will be limited to members of the Board of Directors, members of permanent standing or ad hoc committees, OPTN Contractor staff and individuals engaged as an adjunct to Contractor staff. Access will be limited to the above-described individuals, provided that these individuals are performing functions on behalf of the OPTN and are either bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN Contractor to maintain the confidentiality of such data and information. These individuals will have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information will be a private and confidential matter which is required for the continued success of the OPTN and its business. This Confidential Information includes but is not limited to financial data and information; data and information relating to procedural and substantive needs, problems, developments and projects; and data and information regarding deceased and living organ donors and recipients and institutions and medical personnel involved in organ transplantation, which constitute sensitive medical data or information subject to federal or state confidentiality statutes and regulations, all of which constitute trade secrets or confidential information of the OPTN. All such data and information together with business practices and procedures of the OPTN will be referred to collectively as "Confidential Information."~~

~~At such time as it becomes necessary to present or review candidate and recipient specific or transplant hospital specific data or other Confidential Information, such data or Confidential Information will be provided in individual packets for review at that non-public meeting only. At the conclusion of the meeting all individual packets will be collected by the administrative staff, and no such data or Confidential Information will be permitted outside the meeting room except that maintained by administrative staff and adjunct personnel. When practicable, the Confidential Information will be displayed electronically via overhead projection or slide projection for discussion purposes thereby eliminating the need for individualized sets of the Confidential Information. Only OPTN Contractor staff, or government staff pursuant to contractual requirements, will be able to retain the data or Confidential Information in written or electronic form.~~

~~In no event will any person, other than OPTN Contractor staff and adjunct personnel in attendance in any non-public meeting be permitted to have access to these data or confidential information outside the meeting room. Cooperation and compliance with these procedures will~~



~~ensure the integrity of the OPTN and foster the trust of those who are associated with or who have dealings with the OPTN.~~

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# ***Clarify Time Frames in the OPTN Bylaws regarding Inactivation after Conditional Approval***

**Sponsoring Committee:** Membership and Professional Standards

**Bylaws Affected:** OPTN Bylaws Appendices E.3.G: Conditional Approval for Primary Transplant Physician, F.3.G: Conditional Approval for Primary Transplant Physician, F.7.F: Rejection of Conditional Approval, F.12.B: Rejection of Conditional Approval, G.3.D: Conditional Approval for Primary Transplant Physician, H.3.D: Conditional Approval for Primary Transplant Physician, and I.3.D: Conditional Approval for Primary Transplant Physician

**Public Comment:** N/A

**Effective Date:** March 1, 2016

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## **Problem Statement**

The current Bylaws regarding program inactivation after a period of conditional approval are misleading. Conditional approval of transplant program key personnel can be granted for an initial period (either 12 or 36 months, depending on the program type), and may be extended for up to an additional 6 months or year depending on the type of program. In the language that requires a program to inactivate after their conditional approval ends, the Bylaws reference a specific length (either 12 months, 2 years or 36 months) for the conditional approval period. Since this period can change depending on whether or not it is extended, this proposal would remove the reference to the specific length of time in the inactivation sections so that they simply refer to the end of conditional approval.

Additionally, the paragraph regarding extension or conditional approval currently follows the paragraph regarding inactivation after conditional approval ends. This proposal would switch the order of these paragraphs where applicable so that it is in chronological and logical order.

## **Summary of Changes**

The updated Bylaws remove the reference to the specific length of time in each of the inactivation sections so that they simply refer to the end of conditional approval. In addition, we moved the paragraph in each section that explains extension of a conditional approval so that it is in chronological order, before the paragraph that outlines when inactivation after conditional approval ends.

## **What Members Need to Do**

There is nothing members need to do to implement this proposal. Members with conditional approval, including those that have been granted a conditional approval extension by the MPSC, will still be expected to inactivate at the end of their conditional approval period if they do not meet the requirements for full approval. Members who print out copies of their Policies or Bylaws as reference should print the updated versions.

## Affected Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

### E.3.G Conditional Approval for Primary Transplant Physician

If the primary kidney transplant physician changes at an approved Kidney transplant program, a physician can serve as the primary kidney transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 23 or more newly transplanted kidney recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
4. The physician has 12 months experience on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician should have observed at least 3 organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another kidney transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with

and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections E.3.A through E.3.F* above at the end of the ~~12-month~~ conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.~~

### **F.3.G. Conditional Approval for Primary Transplant Physician**

If the primary liver transplant physician changes at an approved liver transplant program, a physician can serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program, or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a liver. If the physician has completed these

observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
7. The program has established and documented a consulting relationship with counterparts at another liver transplant program.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician sends that details the training and experience the physician gained in liver transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections F.3.A through F.3.F* above at the end of the ~~42-month~~ conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.~~

### **F.7.F Rejection of Conditional Approval**

If the program is unable to demonstrate that it has 2 designated surgeons on site who can fully meet the primary living donor liver surgeon requirements as described above at the end of the ~~2-year~~ conditional approval period, it must stop performing living donor liver recoveries by *either*:

1. Inactivating the living donor component of the program for a period up to 12 months.

2. Relinquishing the living donor component of the liver transplant program until it can meet the requirements for full approval.

### **F.12.B. Rejection of Conditional Approval**

If the program is unable to demonstrate that it has a designated surgeon and physician on site who can fully meet the primary surgeon and primary physician requirements as described above at the end of the ~~36-month~~ conditional approval period, it must stop performing intestine transplants and *either*:

- Inactivate the intestine transplant program for a period up to 12 months
- Withdraw the intestine transplant program until it can meet the requirements for full approval

The requirements for program inactivation and withdrawal are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

### **G.3.D. Conditional Approval for Primary Transplant Physician**

If the primary pancreas transplant physician changes at an approved pancreas transplant program, a physician can serve as the primary pancreas transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or its foreign equivalent. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a pancreas. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient

progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.

7. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the transplant program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.~~

### **H.3.D. Conditional Approval for Primary Transplant Physician**

If the primary heart transplant physician changes at an approved heart transplant program, a physician can serve as the primary heart transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months experience on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.

4. The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
5. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another heart transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or an approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections H.3.A through H.3.C* above at the end of the ~~12-month~~ conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.



~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.~~

### **I.3.D. Conditional Approval for Primary Transplant Physician**

If the primary lung transplant physician changes at an approved lung transplant program, a physician can serve as the primary lung transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician is a pulmonologist with current board certification in pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months of experience on an active lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has been involved in the primary care of 8 or more newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be lung transplant recipients. This care must be documented in a recipient log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
4. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
5. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another lung transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary lung transplant physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising lung transplant physician or surgeon of the training program documenting the physician's competence.
  - b. A letter of recommendation from the training program's primary physician and director outlining the physician's overall qualifications to act as primary transplant physician of the transplant program last served by the physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary

physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual practicing on site who can meet the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the ~~12-month~~ conditional approval period, it must inactivate. The requirements for transplant program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.~~

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# ***Changes to Transplant Program Key Personnel Procurement Requirements***

**Sponsoring Committee: Membership and Professional Standards**

**Bylaws Affected: OPTN Bylaws Appendices E.2.A: Formal 2-year Transplant Fellowship Pathway, E.2.B: Clinical Experience Pathway, E.3.A: Twelve-month Transplant Nephrology Fellowship Pathway, E.3.B: Clinical Experience Pathway, E.3.C: Three-year Pediatric Nephrology Fellowship Pathway, E.3.D: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway, E.3.E: Combined Pediatric Nephrology Training and Experience Pathway, E.3.G: Conditional Approval for Primary Transplant Physician, F.2.A: Formal 2-year Transplant Fellowship Pathway, F.2.B: Clinical Experience Pathway, F.3.A: 12-month Transplant Hepatology Fellowship Pathway, F.3.B: Clinical Experience Pathway, F.3.C: Three-year Pediatric Gastroenterology Fellowship Pathway, F.3.D: Pediatric Transplant Hepatology Fellowship Pathway, F.3.E: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway, F.3.G: Conditional Approval for Primary Transplant Physician, F.10.A: Full Intestine Surgeon Approval Pathway, F.10.B: Conditional Intestine Surgeon Approval Pathway, G.2.A: Formal 2-year Transplant Fellowship Pathway, G.3.A: Twelve-month Transplant Medicine Fellowship Pathway, G.3.B: Clinical Experience Pathway, G.3.D: Conditional Approval for Primary Transplant Physician, H.2.A: Cardiothoracic Surgery Residency Pathway, H.2.B: Twelve-month Heart Transplant Fellowship Pathway, H.3.A: Twelve-month Transplant Cardiology Fellowship Pathway, H.3.B: Clinical Experience Pathway, H.3.D: Conditional Approval for Primary Transplant Physician, I.2.A: Cardiothoracic Surgery Residency Pathway, I.2.B: Twelve-month Lung Transplant Fellowship Pathway, I.3.A: Twelve-month Transplant Pulmonary Fellowship**

## **Pathway, I.3.B: Clinical Experience Pathway, I.3.D: Conditional Approval for Primary Transplant Physician**

**Public Comment:** August 2015

**Effective Date:** Upon implementation and notice to OPTN members

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### **Problem Statement**

Discussions among members of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) and the Joint Societies Working Group (JSWG) highlighted a number of issues related to key personnel procurement requirements in OPTN/UNOS Bylaws. Specifically:

- Experience with procurements involving multi-organ donors is only required of primary kidney transplant surgeons; and separately, experience in donor selection and management is only required of primary liver transplant surgeons. These surgical experiences are not exclusive to each respective organ, and it is not clear why these requirements would be specified for these isolated organs.
- It is generally accepted that primary transplant physicians need to have some familiarity with the organ procurement process. The Bylaws support this, stating that primary transplant physicians “should” have observed three procurements, but there is no way to enforce this expectation because of the word “should.”
- Bylaws pertaining to primary transplant physicians’ exposure to organ procurements state that physicians should have observed three multiple organ donor procurements. The majority of deceased donors today are multi-organ donors. This prompted questions whether the Bylaws still need this level of specificity.
- The MPSC receives primary transplant surgeon applications from individuals applying through this training pathway: they have completed the required number of procurements, but not all of the reported procurements were performed during their training period. The MPSC generally feels these individuals are qualified to serve as the program’s primary transplant surgeon, but is obligated to reject these applications per the current Bylaws requirement.

### **Summary of Changes**

- We deleted the multiple organ procurement requirements that are only found in the primary kidney transplant surgeon pathways and the donor selection and management requirements that are found in the primary liver transplant surgeon and primary intestine transplant surgeon pathways.
- The Bylaws now indicate that primary transplant physicians must (not *should*) observe at least three organ procurements and at least three transplants. These observations must include the organ type that corresponds to the program they are applying to be the primary physician of. Primary kidney physicians are required to observe at least one living donor procurement and at least one deceased donor procurement.
- We deleted the multiple organ donor procurement observation requirement found in each primary transplant physician pathway.
- We changed the primary transplant surgeon fellowship and residency pathways to allow reporting of procurements performed during the two years that immediately follow the completion of their training period, in addition to procurements performed during their training period.

### **What Members Need to Do**

No immediate action is required when the changes are implemented. We will evaluate membership and key personnel change applications that are submitted on or after the changes are implemented according to the new requirements. Currently approved transplant programs will not be impacted by these changes until your circumstances require you to submit a key personnel application change.

### Affected Bylaws Language:

New language is underlined and language that will be deleted is ~~struck through~~.

## ***Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs***

### **E.2 Primary Kidney Transplant Surgeon Requirements**

#### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a 2-year transplant fellowship if the following conditions are met:

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant ~~over the 2-year period~~. At least 3 of these procurements must be multiple organ procurements and at least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters

judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary kidney transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated kidney transplant program, or its foreign equivalent. The transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.
2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first assistant. ~~At least 3 of these procurements must be multiple organ procurements and at least 10 of these procurements must be from deceased donors.~~ These cases must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the transplant program and Chairman of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

## E.3 Primary Kidney Transplant Physician Requirements

### A. Twelve-month Transplant Nephrology Fellowship Pathway

Physicians can meet the training requirements for a primary kidney transplant physician during a separate 12-month transplant nephrology fellowship if the following conditions are met:

1. The physician has current board certification in nephrology by the American Board of Internal Medicine or the foreign equivalent.
2. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
3. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
5. The physician ~~should~~ must have observed at least 3 organ kidney procurements, including at least 1 deceased donor and 1 living donor. ~~and 3 kidney transplants.~~ The physician ~~should~~ also must have observed the evaluation, the donation process, and management of these donors. ~~at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 67 The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and the supervising qualified kidney transplant physician verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance

- protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The training requirements outlined above are in addition to other clinical requirements for general nephrology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary kidney transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a Kidney transplant program or the foreign equivalent. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
3. The physician ~~should~~ must have observed at least 3 organ kidney procurements, including at least 1 deceased donor and 1 living donor. ~~and 3 kidney transplants.~~ The physician ~~should~~ also must have observed the evaluation, the donation process, and management of these donors. ~~at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the kidney transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may



request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

### **C. Three-year Pediatric Nephrology Fellowship Pathway**

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the following conditions must be met:

1. The physician has current board certification in nephrology by the American Board of Pediatrics, or the foreign equivalent.
2. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program's director or the primary physician of the transplant program.
3. The experience caring for pediatric patients occurred with a qualified kidney transplant physician and surgeon at a kidney transplant program that performs an average of at least 10 pediatric kidney transplants a year.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
5. The physician ~~should~~ must have observed at least 3 organ kidney procurements, including at least 1 deceased donor and 1 living donor, and 3 pediatric kidney transplants. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of these donors, at least 3 multiple organ donors who donated a kidney. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
67. The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

#### **D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway**

The requirements for the primary kidney transplant physician can be met during a separate pediatric transplant nephrology fellowship if the following conditions are met:

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another Kidney transplant program in order to meet these requirements. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
3. The experience in caring for pediatric patients occurred at a kidney transplant program with a qualified kidney transplant physician and surgeon that performs an average of at least 10 pediatric kidney transplants a year.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft

recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

5. The physician ~~should~~ must have observed at least 3 ~~organ~~ kidney procurements, including at least 1 ~~deceased donor and 1 living donor~~ and 3 ~~pediatric kidney transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of these donors. ~~of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 6.7 The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to become the primary transplant physician of a designated kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

## **E. Combined Pediatric Nephrology Training and Experience Pathway**

A physician can meet the requirements for primary kidney transplant physician if the following conditions are met:

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and

- tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME or a Residency Review Committee.
5. The physician ~~should~~ must have observed at least 3 ~~organ kidney procurements, including at least 1 deceased donor and 1 living donor. and 3 pediatric kidney transplants.~~ The physician ~~should also~~ must have observed the evaluation, the donation process, and management of ~~these donors. at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
  6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  67. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
    - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

## **G. Conditional Approval for Primary Transplant Physician**

If the primary kidney transplant physician changes at an approved Kidney transplant program, a physician can serve as the primary kidney transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 23 or more newly transplanted kidney recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the last 2 years. This includes

the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.

4. The physician has 12 months experience on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician ~~should~~ must have observed at least 3 ~~organ kidney procurements, including at least 1 deceased donor and 1 living donor, and 3 kidney transplants.~~ organ kidney procurements, including at least 1 deceased donor and 1 living donor. The physician ~~should also~~ must have observed the evaluation, the donation process, and management of these donors. ~~at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 67 The program has established and documented a consulting relationship with counterparts at another kidney transplant program.
- 78 The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
- 89 The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## ***Appendix F: Membership and Personnel Requirements for Liver Transplant Programs***

### **F.2 Primary Liver Transplant Surgeon Requirements**

#### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary liver transplant surgeon by completing a 2-year transplant fellowship if the following conditions are met:

1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant ~~during the 2-year period. At least 3 of these procurements must include selection and management of the donor.~~ These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in *Section F.5. Approved Liver Surgeon Transplant Fellowship Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.

- b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
- c. A letter from the surgeon that details his or her training and experience in liver transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary liver transplant surgeon through clinical experience gained post-fellowship, if the following conditions are met:

1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated liver transplant program, or its foreign equivalent. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of liver transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative management of liver recipients.
2. The surgeon has performed at least 30 liver procurements as primary surgeon or first assistant. ~~At least 3 of these procurements must include selection and management of the donor.~~ These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The following letters are sent directly to the OPTN Contractor:
  - a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- c. A letter from the surgeon that details the training and experience the surgeon gained in liver transplantation.

### F.3 Primary Liver Transplant Physician Requirements

#### A. 12-month Transplant Hepatology Fellowship Pathway

Physicians can meet the training requirements for a primary liver transplant physician during a separate 12-month transplant hepatology fellowship if the following conditions are met:

1. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program. The training must have included at least 3 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted liver recipients, and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of these donors. ~~at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
56. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and the supervising liver transplant physician verifying that the physician has met the above requirements and is qualified to direct a liver transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or



others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician writes that details the training and experience the physician gained in liver transplantation.

The training requirements outlines above are in addition to other clinical requirements for general gastroenterology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary liver transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 50 or more newly transplanted liver recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program or the foreign equivalent. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
3. The physician ~~should~~ must have observed at least 3 ~~organ liver procurements and 3 liver transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the donation process, and management of these donors, at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, the location of the donor, and Donor ID.
4. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the liver transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,

and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

### C. Three-year Pediatric Gastroenterology Fellowship Pathway

A physician can meet the requirements for primary liver transplant physician by completion of 3 years of pediatric gastroenterology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain at least 6 months of clinical care for transplant patients, and meet the following conditions:

1. The physician has current board certification in gastroenterology by the American Board of Pediatrics, or the foreign equivalent.
2. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along with a qualified liver transplant surgeon. The physician was also directly involved in the preoperative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience carried out at another transplant service, to meet these requirements. This care must be documented in a log that includes the date of transplant, the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program's primary transplant physician.
3. The experience caring for pediatric patients occurred at a liver transplant program with a qualified liver transplant physician and a qualified liver transplant surgeon that performs an average of at least 10 liver transplants on pediatric patients per year.
4. The physician ~~should~~ must have observed at least 3 organ liver procurements ~~and 3 liver transplants. In addition, the~~ The physician should also must have observed the evaluation, the donation process, and management of these donors. -at least 3 multiple organ donors who donated a liver. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
5. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
56. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term

outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.

67. The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the director of the pediatric gastroenterology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

#### **D. Pediatric Transplant Hepatology Fellowship Pathway**

The requirements for primary liver transplant physician can be met during a separate pediatric transplant hepatology fellowship if the following conditions are met:

1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for at least 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience completed at another liver transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
3. The experience in caring for pediatric liver patients occurred at a liver transplant program with a qualified liver transplant physician and surgeon that performs an average of at least 10 pediatric liver transplants a year.
4. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft

- recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver transplants~~. ~~In addition, the~~ The physician should also must have observed the evaluation, ~~the~~ donation process, and management of ~~these donors~~. ~~at least 3 multiple organ donors who donated a liver~~. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
  6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  67. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
    - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## **E. Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway**

A physician can meet the requirements for primary liver transplant physician if the following conditions are met:

1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and along with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver transplants recipients. This care must be documented in a log that includes at the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.

4. The individual has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver transplants~~. ~~In addition, the~~ The physician should also must have observed the evaluation, ~~the~~ donation process, and management of ~~these donors~~, ~~at least 3 multiple organ donors who donated a liver~~. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
67. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## **G. Conditional Approval for Primary Transplant Physician**

If the primary liver transplant physician changes at an approved liver transplant program, a physician can serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the

- OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
  4. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program, or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
  5. The physician ~~should~~ must have observed at least 3 ~~organ~~ liver procurements ~~and 3 liver transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of these donors. ~~of at least 3 multiple organ donors who are donating a liver. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
  6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - ~~67.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
  - ~~78.~~ The program has established and documented a consulting relationship with counterparts at another liver transplant program.
  - ~~89.~~ The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
    - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician sends that details the training and experience the physician gained in liver transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections F.3.A through F.3.F* above at the end of the 12 month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## **F.10 Primary Intestine Transplant Surgeon Requirements**

### **A. Full Intestine Surgeon Approval Pathway**

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

1. The surgeon performed 7 or more intestine transplants to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. ~~These procurements must include selection and evaluation of the donor.~~ These procurements must include 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in *Section F.13 Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted to the OPTN Contractor:
  - a. A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.

- b. A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

## **B. Conditional Intestine Surgeon Approval Pathway**

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel and composite grafts and must perform 3 or more intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program, or its foreign equivalent. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.
2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first assistant. These procurements must include at least 1 procurement of a graft that includes a liver, ~~and selection and evaluation of the donor~~. This procedure must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.
5. The following letters are sent to the OPTN Contractor:
  - a. A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.



- c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
- d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

## ***Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs***

### **G.2 Primary Pancreas Transplant Surgeon Requirements**

#### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary pancreas transplant surgeon by completing a 2-year transplant fellowship if the following conditions are met:

1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant ~~during the 2-year period~~. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These cases must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a pancreas transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows. Foreign training programs will be reviewed by the MPSC and only those programs that are accepted as equivalent will be granted approval.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
  - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary

transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

### G.3 Primary Pancreas Transplant Physician Requirements

#### A. Twelve-month Transplant Medicine Fellowship Pathway

Physicians can meet the training requirements for a primary pancreas transplant physician during a separate 12-month transplant medicine fellowship if the following conditions are met:

1. The physician completed 12 consecutive months of specialized training in pancreas transplantation at a pancreas transplant program under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon. The training must have included at least 6 months on the clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 8 or more newly transplanted pancreas recipients and followed these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be identified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
4. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3 pancreas transplants~~. The physician ~~should~~ must have observed the evaluation, ~~the~~ donation process, and management of ~~these donors at least 3 multiple organ donors who donated a pancreas. If the physician completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
- ~~5~~6. The curriculum of this transplant medicine fellowship should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
- ~~6~~7. The following letters are submitted directly to the OPTN Contractor:

- a. A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
- b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program that the physician previously served, at its discretion.
- c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The above training is in addition to other clinical requirements for general nephrology, endocrinology, or diabetology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a pancreas transplant program, or its foreign equivalent. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3 pancreas transplants~~. The physician ~~should~~ must have also observed the evaluation, the donation process, and management of ~~these donors~~, ~~at least 3 multiple organ donors who donated a pancreas~~. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.

45. The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program the physician previously served, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary pancreas transplant physician changes at an approved pancreas transplant program, a physician can serve as the primary pancreas transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or its foreign equivalent. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3 pancreas transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation process, and management of ~~these donors~~. ~~at least 3 multiple organ donors who are donating a pancreas~~. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.

56. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
67. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.
78. The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the transplant program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## ***Appendix H: Membership and Personnel Requirements for Heart Transplant Programs***

### **H.2 Primary Heart Transplant Surgeon Requirements**

#### **A. Cardiothoracic Surgery Residency Pathway**

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a cardiothoracic surgery residency if *all* the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the cardiothoracic surgery residency. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon ~~during the cardiothoracic surgery residency~~. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

## **B. Twelve-month Heart Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a 12-month heart transplant fellowship if the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon ~~during the 12-month heart transplant fellowship~~. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in a log that includes the date of

- procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
  4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
    - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### H.3 Primary Heart Transplant Physician Requirements

#### A. Twelve-month Transplant Cardiology Fellowship Pathway

Physicians can meet the training requirements for primary heart transplant physician during a 12-month transplant cardiology fellowship if the following conditions are met:

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients. This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician ~~should~~ must have observed at least 3 organ heart procurements ~~and 3 heart transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the donation process, and management of these donors. 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

4. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology or American Board of Pediatrics certified fellowship training program in pediatric cardiology or its foreign equivalent, as accepted by the MPSC.
56. The following letters are submitted directly to the OPTN Contractor:
- A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
  - A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the Primary Physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - A letter from the physician that details the training and experience the physician has gained in heart transplantation.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

- The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program or its foreign equivalent. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
- The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
- The physician ~~should~~ must have observed at least 3 ~~organ heart~~ procurements and ~~3 heart transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation process, and management of these donors. ~~3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.



4. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. The following letters are submitted directly to the OPTN Contractor:
- A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - A letter from the physician that details the training and experience the physician has gained in heart transplantation.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary heart transplant physician changes at an approved heart transplant program, a physician can serve as the primary heart transplant physician for a maximum of 12 months if the following conditions are met:

- The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
- The physician has 12 months experience on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
- The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
- The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
- The physician ~~should~~ must have observed at least 3 ~~organ heart~~ procurements ~~and 3 heart transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation process, and management of these donors. ~~at least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

6. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
67. The program has established and documented a consulting relationship with counterparts at another heart transplant program.
78. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.
89. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or an approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

# ***Appendix I: Membership and Personnel Requirements for Lung Transplant Programs***

## **I.2 Primary Lung Transplant Surgeon Requirements**

### **A. Cardiothoracic Surgery Residency Pathway**

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a cardiothoracic surgery residency if the following conditions are met:

1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or heart/lung transplants as primary surgeon or first assistant under the direct supervision of a qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung transplant program. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must also include the other clinical requirements for thoracic surgery.
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

## B. Twelve-month Lung Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a 12-month lung transplant fellowship if the following conditions are met:

1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the program.
2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon ~~during the 12-month lung transplant fellowship~~. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

## I.3 Primary Lung Transplant Physician Requirements

### A. Twelve-month Transplant Pulmonary Fellowship Pathway

Physicians can meet the training requirements for primary lung transplant physician during a 12-month transplant pulmonary fellowship if the following conditions are met:

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct

supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.

2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3 lung transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of these donors. ~~3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
56. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for primary lung transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 15 or more newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period on an active lung

- transplant program or its foreign equivalent. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
  3. The physician ~~should~~ must observe at least 3 lung or heart/lung procurements ~~and 3 lung transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the donation process, and management of these donors.~~ ~~3 multiple organ donors who are donating a lung or heart/lungs.~~ ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
  4. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  45. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
    - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary lung transplant physician changes at an approved lung transplant program, a physician can serve as the primary lung transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician is a pulmonologist with current board certification in pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months of experience on an active lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has been involved in the primary care of 8 or more newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct

supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be lung transplant recipients. This care must be documented in a recipient log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.

4. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
5. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3 lung transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation process, and management of these donors. ~~3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
- ~~67.~~ The program has established and documented a consulting relationship with counterparts at another lung transplant program.
- ~~78.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary lung transplant physician by the end of the 12 month conditional approval period.
- ~~89.~~ The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising lung transplant physician or surgeon of the training program documenting the physician's competence.
  - b. A letter of recommendation from the training program's primary physician and director outlining the physician's overall qualifications to act as primary transplant physician of the transplant program last served by the physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual practicing on site who can meet the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for transplant program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

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# ***Proposal to Reduce the Documentation Shipped with Organs***

**Sponsoring Committee:** Organ Procurement Organization

**Policy/Bylaws Affected:** Policies 2.2: OPO Responsibilities, 16.1: Organs Recovered by Living Donor Recovery Hospitals, and 16.4: Documentation Accompanying the Organ or Vessel

**Public Comment:** August 2015

**Effective Date:** March 1, 2016

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## **Problem Statement**

The OPTN/UNOS organ documentation policy (16.4.A) states that members must include the complete donor record in the container with each transported organ. These requirements originated before OPOs had access to electronic medical records and could upload information into DonorNet®. During the TransNet<sup>sm</sup> project, the project team discovered that the amount of time coordinators spent making copies of donor record documents took their time and attention away from critical, time-sensitive aspects of their job. Including these documents, most of which were already in DonorNet, in the package with the organ was inefficient, redundant, and a potential safety hazard because it took their attention away from donor management. The current requirements can also delay the departure of the transplant teams and unnecessarily increase cold ischemic time.

## **Summary of Changes**

The only source documentation that must accompany each organ is blood type, blood subtype (if used for allocation), and infectious disease testing results. When transplant programs receive the organ, they must upload to DonorNet® this information along with documentation for the death pronouncement, authorization for donation, human leukocyte antigen (HLA) type, donor evaluation and management, donor medical and behavioral history, and organ intraoperative findings. We also modified Policy 16.1 to address a conflict with Policy 16.4 regarding living donor documentation that accompany living donor organs.

## **What Members Need to Do**

Nothing will immediately change for OPOs even after this policy is implemented because the Centers for Medicare & Medicaid Services (CMS) still requires you to send complete donor documentation with the organs. UNOS will work with HRSA and CMS to make these OPTN and CMS requirements consistent. Once this happens, OPOs will upload all donor information to DonorNet as usual. Transplant hospitals will need to be aware that donor information is available in DonorNet and that OPOs will only include the blood type and infectious disease source documentation in the shipping container with each organ. If transplant hospitals need paper copies they can print the DonorNet information.

We will let you know in advance whenever our requirements and CMS requirements are in alignment.

## Affected Policy Language:

New language is underlined and language that will be deleted is ~~struck through~~.

## 2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
- ~~11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.~~
- ~~12.~~ 11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
- ~~13.~~ 12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
- ~~14.~~ 13. Ensuring that ~~written~~ documentation for all of the following deceased donor information is submitted to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs: of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
  - a. ABO source documentation
  - b. ABO subtype source documentation
  - c. Infectious disease results source documentation
  - d. Death pronouncement source documentation
  - e. Authorization for donation source documentation
  - f. Human leukocyte antigen (HLA) type
  - g. Donor evaluation and management
  - h. Donor medical and behavioral history
  - i. Organ intraoperative findings
- ~~15.~~ 14. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

## 16.1 Organs Recovered by Living Donor Recovery Hospitals

Living donor recovery hospitals must follow all of the requirements for packaging, labeling, and transporting organs, tissue typing material, and vessels according to this Policy, with these

differences:

1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, vessels, and tissue typing samples.
2. When a member repackages a living donor organ, they are not required to notify the member that originally packaged the organ.
3. ~~Instead of~~ In addition to the list of documents in *Policy 16.4: Documentation Accompanying the Organ or Vessel*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Vessels that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.
4. Blood samples must contain the donor ID and *one* of the following three identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.
5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

## 16.4 Documentation Accompanying the Organ or Vessel

### 16.4.A Organ Packaging Documentation Requirements

Each external ~~deceased and living donor~~ transport container holding an organ must be sent with ~~the complete deceased and living donor record that includes~~ all of the following source documentation:

1. Blood type ~~source documentation~~
2. Blood subtype ~~source documentation~~, if used for allocation
3. Infectious disease testing results available at the time of organ packaging
4. ~~Medical and behavioral history information~~
5. ~~Donor evaluation information~~
6. ~~Donor authorization form~~
7. Organ quality information as noted in *Policy 2.15.C: Organ Procurement Procedures*

~~Donor~~ The source documentation must be placed in a watertight container in *either* of the following:

- A location specifically designed for documentation
- Between the inner and external transport containers

~~When a deceased or living donor organ is transported, the host OPO or the transplant hospital must include the source documentation with the donor information.~~

#

# Proposal to Increase OPTN/UNOS Committee Terms to Three Years

**Sponsoring Committee:** Policy Oversight

**Policy/Bylaws Affected:** OPTN Bylaws Article VII, Sections 7.2: Standing Committee Chairs, 7.3: Terms of Standing Committee Members, and 7.5: The Policy Oversight Committee (POC)

**Public Comment:** August 2015

**Effective Date:** March 1, 2016

## Problem Statement

Currently committee members have two-year terms, except for Patient Affairs (PAC), Ethics, and Transplant Administrators Committee (TAC) members who serve three-year terms. In spring 2015, we asked the committees if they thought a two-year term gave them enough time to complete larger projects. Committee members with current two-year terms voted almost unanimously to extend terms to three years. Those who already serve three-year terms thought that was the appropriate amount of time. Examples of recent large projects that have taken longer than two-years to complete include KAS (Kidney Allocation System), ABO Blood Typing Requirements, and Revisions to LAS (Lung Allocation System).

Two-year terms also require that half of the committee be educated and oriented on their committee duties each year. This is inefficient and may cause committees to lose important expertise and historical knowledge.

## Summary of Changes

This project will affect all committee members except TAC, PAC, Ethics, and Membership and Professional Standards (MPSC), who will see no change in their current committee terms. The following table summarizes committee term lengths:

<p><b>Two Year Terms</b></p>	<ul style="list-style-type: none"> <li>• <b>All</b> Membership and Professional Standards Committee (MPSC) members</li> <li>• <b>Chairs and Vice Chairs</b> of the Ad Hoc Disease Transmission Advisory, Ad Hoc International Relations, Data Advisory, Histocompatibility, Living Donor, Kidney, Liver, Minority Affairs, Operations and Safety, OPO, Pancreas, Pediatric, Thoracic, Transplant Coordinators and VCA Committees</li> </ul>
<p><b>Three Year Terms</b></p>	<ul style="list-style-type: none"> <li>• <b>All members</b> of Ad Hoc Disease Transmission Advisory, Ad Hoc International Relations, Data Advisory, Ethics, Histocompatibility, Kidney, Liver, Living Donor, Minority Affairs, Operations and Safety, OPO, Pancreas, Patient Affairs, Pediatric, Thoracic, Transplant Administrators, Transplant Coordinators, and VCA Committees</li> <li>• <b>Chairs and Vice Chairs</b> of Patient Affairs, Ethics, and Transplant Administrators Committees.</li> </ul>

## What Members Need to Do

There is nothing members need to do to implement this proposal. UNOS staff will educate all potential and new committee members that when they volunteer for a committee they are committing to serve a three-year term. They will also communicate that leadership terms are two-years each for the Vice Chair and Chair, except for PAC, TAC, and Ethics.

### Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

## 7.2 Permanent Standing Committee Chairs and Vice Chairs

Committee Chairs inform the OPTN president and the Executive Director of the activities of their Committees and report to the Board of Directors upon request.

The treasurer of the OPTN serves as the Chair of the Finance Committee. The vice president, with approval of the Board of Directors, appoints the Chair of the other permanent standing Committees.

Chairs and Vice Chairs of the permanent standing Committees have the following terms:

- The Patient Affairs, Ethics and Transplant Administrator Chairs and Vice Chairs serve three-year terms.
- Other Chairs and Vice Chairs serve two-year terms.

Chairs will serve an additional 1-year term as an *ex-officio* member of the Committee.

The vice president may appoint one or more Committee Chairs for a one-year term so that a staggered rotation is achieved. Committee Chairs may be appointed to consecutive terms. The president will appoint the replacement for any Chairs or Vice Chairs who cannot complete their full term for any reason.

## 7.3 Terms of Permanent Standing Committee Members

The vice president appoints members of the Committees for terms of ~~two~~three years, except for ~~the Patient Affairs, Ethics and Transplant Administrators Committee~~ Membership and Professional Standards Committee (MPSC) members, who serve ~~three~~two-year terms. When appointing permanent standing Committee members, the vice president may also:

- Appoint up to one-~~third~~half of the members of a Committee to a one-year term to achieve a staggered rotation.
- Appoint any Committee member to an additional full or partial ~~consecutive~~ term whose expertise is needed for the Committee to continue its work.

The president will appoint the replacement for any Committee members who cannot complete their full term for any reason. Committee terms begin on July 1.

## 7.5 The Policy Oversight Committee (POC)

The OPTN will have a permanent standing committee, the Policy Oversight Committee (POC), that The POC will be advisory to the Board of Directors. The POC will also provide written recommendations about policies to the Board of Directors at least twice a year.

- ~~■ Provide written recommendations about policies to the Board of Directors at least twice a year.~~
- ~~■ Review and comment on research projects being conducted and published by the OPTN and the Scientific Registry of Transplant Recipients (SRTR).~~
- ~~■ Work in collaboration with the SRTR Technical Advisory Committee (STAC) to identify and develop SRTR research priorities.~~

### A. Composition of POC

The POC will be comprised of the Vice Chairs of the organ-related and constituency Committees each of the Committees, or a representative of each Committee appointed by the vice president, and the following other individuals as needed members:

- ~~1. Two public policy or public health representatives, with strong backgrounds in healthcare policy analysis.~~
- ~~2. Representatives from the public including transplant recipients, candidates, donors and their families.~~
- ~~3. Two professionals with expertise in applying research data to policy chosen by the SRTR.~~
- ~~4. Other individuals, as needed.~~

### B. Ex-officio Representation

The Policy Oversight Committee will also have *ex-officio* members from the Division of Transplantation of the HHS and the Scientific Registry of Transplant Recipients (SRTR), or representatives they designate, as follows:

1. The U.S. Health Resources and Services Administration (HRSA) Project Officer for the OPTN contract.
2. The Director of the Division of Transplantation.
3. One other Federal representative to be designated by the OPTN Project Officer.
4. The Project Officer of the SRTR contract.
5. Two *ex-officio*, non-voting representatives of the SRTR, chosen by the SRTR.

~~Current members of the OPTN Board of Directors may not serve on this Committee.~~

### C. POC Chair

~~The president vice president, with approval of the Board of Directors, will appoint the Chair and Vice Chair of the POC for two-year terms the Chair of the POC. POC Chairs and Vice Chairs may be appointed to consecutive terms. The POC Chair will also serve an additional 1-year term as an *ex-officio* member of the Committee.~~

### CD. Terms of POC Members

~~With the exception of the MPSC Vice Chair, aAll POC members, except the Chair or standing Committee Vice Chairs, serve *ex-officio* on the Policy Oversight Committee . All other members~~

of the POC serve for terms equal to the term they are serving on the Committee they are representing. POC terms begin on July 1.

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# ***Update to the Human Leukocyte Antigens (HLA) Equivalency Tables***

**Sponsoring Committee:** Histocompatibility

**Policy/Bylaws Affected:** Policy 2.11.A: Required Information for Deceased Kidney Donors, Policy 2.11.B: Required Information for Deceased Liver Donors, 2.11.C: Required Information for Deceased Heart Donors, 2.11.D: Required Information for Deceased Lung Donors, 2.11.E: Required Information for Deceased Pancreas Donors, 4.1: Requirements for Laboratory Review of Reports, 4.2: Requirements for Waiting list Data Verification, 4.3: Requirements for Performing and Reporting HLA Typing, 4.4: Resolving Discrepant Donor and Recipient HLA Results, 4.5: Antibody Screening and Reporting, 4.6: Crossmatching, 4.7: Blood Type Determination, 4.8: Preservation of Excess Specimens, 4.9: HLA Antigen Values and Split Equivalences, Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences, 13.5.A: HLA Typing Requirements for OPTN KPD Candidates, and 13.5.C: HLA Typing Requirements for OPTN KPD Donors

**Public Comment:** August 2015

**Effective Date:** All policies listed above except for 4.9 and 4.10 will be effective March 1, 2016. Policies 4.9 and 4.10 will be effective pending implementation and notice to OPTN members.

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## **Problem Statement**

This proposal addresses four different issues:

1. Updates the Equivalency Tables as required by OPTN Policy
2. Adds new alleles to the HLA antigen dropdown in UNet<sup>SM</sup>
3. Updates terminology to reflect modern terminology
4. Removes duplicative sections of HLA policy

Policy 4.7: HLA Antigen Values and Split Equivalences, states: "The Histocompatibility Committee must review and recommend any changes needed to the tables on or before June 1 of each year." The Board of Directors last approved updates to the Equivalency Tables in November 2013. Since that time, additional updates to the equivalencies have been proposed and will be incorporated into these tables in policy.

This proposal also adds additional alleles (subtypes) to the HLA antigen dropdown options in UNet to increase access to transplant for sensitized candidates and improve identification of zero antigen mismatches. Current dropdowns are unnecessarily disadvantaging candidates who have antibodies against some but not all alleles in a single antigen group. For these patients, members currently can only list corresponding antigens (inclusive of all alleles in the group) as unacceptable antigens, excluding candidates from a broader donor pool than necessary. In addition, candidates with an allele specific



antibody that is in the same antigen group as their own allele cannot have the unacceptable allele or the antigen listed (for example, candidate type: B\*44:02; unacceptable allele, B\*44:03).

Additionally, current policy references HLA-DPB, HLA-DQA, and HLA-DQB. This terminology is not medically accurate as defined by accepted terminology from the World Health Organization and the genetics community. Therefore, the Committee also proposes updating references to these HLA loci in policy to HLA-DPB1, HLA-DQA1, and HLA-DQB1 to distinguish them from other closely related loci, and to reflect commonly accepted practices within the histocompatibility community.

Lastly, in November of 2014, the Board passed a proposal to expand the Deceased Donor HLA Types. This proposal added Policy 4.4: *Requirements for Performing and Reporting HLA Typing*, which was meant to replace current Policy 4.1: *HLA Typing*. However, section 4.1 was never stricken from policy. This proposal removes the current Policy 4.1, and adds references to pancreas and pancreas islet HLA requirements in Policy 4.4 so that they are aligned with Policy 3.4.D: *Candidate Human Leukocyte Antigen (HLA) Requirements*.

## Summary of Changes

This proposal makes the following changes to policy:

- Changes all references of HLA- DPB, DQA, and DQB to DPB1, DQA1, and DQB1, respectively
- Adds alleles to the HLA- DR51, DR52, and DR53 dropdown menus in UNet
- Updates matching antigen equivalencies and unacceptable antigens in all tables
- Removes duplicative Policy 4.1: *HLA Typing*
- Adds pancreas and pancreas islet references to Policy 4.3: *Requirements for Performing and Reporting HLA Typing*.

## What Members Need to Do

All OPTN members and vendors will need to familiarize themselves with these changes. Transplant programs may need to request updated HLA typing using molecular methods for existing candidates who may be disadvantaged by the changes to the HLA Matching Equivalences tables, especially for any candidate who has a 'broad' antigen listed in their reported HLA type.

Histocompatibility labs will be required to assign antigens less broadly to candidates than in the past. Members may also need to review and modify unacceptable antigens reported for candidates with antibodies against alleles that are being added.

## Affected Policy/Bylaw Language

New language is underlined and language that will be deleted is ~~struck through~~.

## 2.11 Required Deceased Donor Information

### 2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria

8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers.
11. Indications of sepsis
12. Injuries to or abnormalities of the blood
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

### **2.11.B Required Information for Deceased Liver Donors**

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

1. Donor name
2. Donor ID
3. Ethnicity
4. Height
5. Weight
6. Vital signs, including blood pressure, heart rate and temperature
7. Social history, including drug use
8. History of treatment in hospital including current medications, vasopressors, and hydration
9. Current history of hypotensive episodes, urine output, and oliguria
10. Indications of sepsis
11. Aspartate aminotransferase (AST)
12. Bilirubin (direct)
13. Other laboratory tests within the past 12 hours including:
  - a. Alanine aminotransferase (ALT)
  - b. Alkaline phosphatase
  - c. Total bilirubin
  - d. Creatinine
  - e. Hemoglobin (hgb) and hemocrit (hct)
  - f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and partial thromboplastin time (PTT)
  - g. White blood cell count (WBC)
14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program

If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.

### **2.11.C Required Information for Deceased Heart Donors**

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height

2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA<sub>1</sub>, DQB<sub>1</sub>, and DPB<sub>1</sub> antigens prior to the final organ acceptance
11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital

For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information required in the list above and document that the information was provided to the transplant program.

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

#### **2.11.D Required Information for Deceased Lung Donors**

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of medical treatment in hospital including vasopressors and hydration
5. Smoking history
6. Cardiopulmonary, social, and drug activity histories
7. Arterial blood gases and ventilator settings on 5 cm/H<sub>2</sub>O/PEEP including PO<sub>2</sub>/FiO<sub>2</sub> ratio and preferably 100% FiO<sub>2</sub>, within 2 hours prior to the offer
8. Bronchoscopy results
9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
10. Details of any documented cardiac arrest or hypotensive episodes
11. Sputum gram stain, with description of sputum
12. Electrocardiogram
13. Echocardiogram, if the OPO has the facilities
14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA<sub>1</sub>, DQB<sub>1</sub>, and DPB<sub>1</sub> antigens prior to final organ acceptance

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.6.B: Time Limit for Acceptance* are maintained.

For lung deceased donors, if a transplant hospital requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information required in the list above and document that the information was provided to the transplant program.

The lung recovery team must have the opportunity to speak directly with the responsible ICU

personnel or the onsite OPO donor coordinator in order to obtain current information about the deceased donor's physiology.

### **2.11.E Required Information for Deceased Pancreas Donors**

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase
15. Serum lipase
16. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers.

## **4.1 HLA Typing**

### **4.1.A Requirements for Performing and Reporting HLA Typing**

~~Laboratories must do *all* of the following:~~

- ~~1. Perform HLA typing on all potential transplant recipients and donors when requested by a physician or other authorized individuals.~~
- ~~2. Ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the turnaround time specified in the written agreement between the laboratory and any affiliated OPO or transplant program.~~
- ~~3. Report serological split level and molecular typing results to the OPO for all required HLA types according to Table 4.1 *HLA Typing Requirements for Deceased Donors Policy 2.11: Required Deceased Donor Information*, whenever the lab performs HLA typing on deceased kidney, kidney pancreas, and pancreas donors.~~
- ~~4. Report HLA typing results to the Transplant Program for all required HLA types, according to Table 4.21 *HLA Typing Requirements for Candidates*, whenever the laboratory performs HLA typing on candidates.~~

~~Table 4.1 shows HLA types required to be reported for deceased donors.~~

**Table 4.1: HLA Typing Requirements for Deceased Donors**

Organ	A	B	Bw4	Bw6	C	DR	DR51	DR52	DR53	DPB	DQB
Kidney	●	●	●	●	●	●	●	●	●	●	●
Pancreas	●	●	●	●	●	●	●	●	●	●	●
Kidney-Pancreas	●	●	●	●	●	●	●	●	●	●	●
Heart*	●	●	●	●	●	●	●	●	●	●	●
Lung*	●	●	●	●	●	●	●	●	●	●	●

\* For deceased heart and lung donors, if a transplant hospital requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document this request. The OPO must provide the HLA information required in the table above and document that the information was provided to the transplant program. The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.

Table 4.21 shows HLA types required to be reported for candidates.

**Table 4.21: HLA Typing Requirements for Candidates**

Organ	A	B	Bw4	Bw6	DR
Kidney alone	●	●	●	●	●
Pancreas alone	●	●	●	●	●
Kidney-Pancreas	●	●	●	●	●

## 4.21 Requirements for Laboratory Review of Reports

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

### 4.4.3.A Deceased Donor HLA Typing

If the laboratory performs HLA typing on a deceased donor, the laboratory must perform molecular typing and report results at the level of serological splits to the OPO for all required HLA types on deceased donors according to Table 4-31 Deceased Donor HLA Typing Requirements.

Table 4-31 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens.

**Table 4-31: Deceased Donor HLA Typing Requirements**

If a Laboratory Performs HLA Typing on a:	Then the Laboratory Must Report Results to the OPO at the Following Times:
Deceased Kidney, Kidney-Pancreas, <u>Pancreas</u> , or Pancreas <u>Islet</u> Donor	Prior to organ offers
Deceased Heart, Heart-Lung, or Lung Donors	Prior to final acceptance, if required by the transplant program
Deceased Liver Donors	Within the period specified by the transplant program

#### **4.4.3.B HLA Typing for Candidates**

Laboratories must perform HLA typing on a kidney, kidney-pancreas, pancreas, or pancreas islet candidate and report results for HLA A, B, Bw4, Bw6, and DR to the transplant program prior to registration on the waiting list.

### **4.5.4 Resolving Discrepant Donor and Recipient HLA Typing Results**

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

### **4.10.9 HLA Antigen Values and Split Equivalences**

HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in *Policy 4.140: Reference Tables of HLA Antigen Values and Split Equivalences*. The Histocompatibility Committee must review and recommend any changes needed to the tables on or before June 1 of each year. For matching purposes, split antigens not on this list will be indicated on the waiting list as the parent antigens and will match only with the corresponding parent antigens.

### **4.11.10 Reference Tables of HLA Antigen Values and Split Equivalences**

~~Tables 4-32, 4-43, and 4-54, show patient-candidate-donor antigen combinations and whether they are mismatches. For each candidate antigen, the donor antigens that are not mismatched are listed below. All other combinations are considered mismatches. Antigens with an \* indicate an allele that may not have a World Health Organization (WHO)-approved serologic specificity. Antigens given \*\*99 means the patient locus was not tested.~~

**Table 4-32 HLA A Matching Antigen Equivalences**

Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens	Patient A Locus Antigen	Equivalent Donor Antigens
1	1	9	9	<u>2402</u>	<u>2402, 24</u>
2	2, <u>0201</u> , <u>0202</u> , <u>0203</u> , <u>0205</u> , <u>0206</u>	10	10	<u>2403</u>	<u>2403, 24</u>
<u>0201</u>	<u>0201, 2</u>	11	11, <u>1101</u> , <u>1102</u>	25	25
<u>0202</u>	<u>0202, 2</u>	<u>1101</u>	<u>1101, 11</u>	26	26
<u>0203</u>	<u>0203, 2</u>	<u>1102</u>	<u>1102, 11</u>	28	28
<u>0205</u>	<u>0205, 2</u>	19	19	29	29, <u>2901</u> , <u>2902</u>
<u>0206</u>	<u>0206, 2</u>	23	23	<u>2901</u>	<u>2901, 29</u>
3	3	24	24, <u>2402</u> , <u>2403</u>	<u>2902</u>	<u>2902, 29</u>

Patient A Locus Antigen	Equivalent Donor Antigens
30	30, 3001, 3002
<u>3001</u>	<u>3001, 30</u>
<u>3002</u>	<u>3002, 30</u>
31	31
32	32
33	33, 3301, 3303
<u>3301</u>	<u>3301, 33</u>
<u>3303</u>	<u>3303, 33</u>
34	34

Patient A Locus Antigen	Equivalent Donor Antigens
<u>3401</u>	<u>3401, 34</u>
<u>3402</u>	<u>3402, 34</u>
36	36
43	43
66	66, *6601, *6602
<u>6601</u>	<u>6601, 66</u>
<u>6602</u>	<u>6602, 66</u>
68	68, 6801, 6802
<u>6801</u>	<u>6801, 68</u>

Patient A Locus Antigen	Equivalent Donor Antigens
<u>6802</u>	<u>6802, 68</u>
69	69
74	74
80	80
<del>203</del>	<del>203, 2</del>
<del>210</del>	<del>210, 2</del>
<del>2403</del>	<del>2403, 24</del>
<del>*6601</del>	<del>*6601, 66</del>
<del>*6602</del>	<del>*6602, 66</del>
<del>** 99</del>	(No equivalent)

**Table 4-43: HLA B Matching Antigen Equivalences**

Patient B Locus Antigen	Equivalent Donor Antigens
5	5
7	7, 703, 0702
<u>0702</u>	<u>0702, 7</u>
8	8
<u>0802</u>	<u>0802</u>
<u>0803</u>	<u>0803</u>
<u>0804</u>	<u>0804</u>
12	12
13	13, 1301, 1302
<u>1301</u>	<u>1301, 13</u>
<u>1302</u>	<u>1302, 13</u>
14	14, 64, 65
<u>1401</u>	<u>1401, 64</u>
<u>1402</u>	<u>1402, 65</u>
15	15
<u>1501</u>	<u>1501, 62</u>
<u>1502</u>	<u>1502, 75</u>
<u>1503</u>	<u>1503, 72</u>
<u>1510</u>	<u>1510, 71</u>
<u>1511</u>	<u>1511, 75</u>
<u>1512</u>	<u>1512, 76</u>
<u>1513</u>	<u>1513, 77</u>
<u>1516</u>	<u>1516, 63</u>
<u>1517</u>	<u>1517, 63</u>
16	16

Patient B Locus Antigen	Equivalent Donor Antigens
17	17
18	18
21	21
22	22
27	27, 2705
<u>2705</u>	<u>2705, 27</u>
<u>2708</u>	<u>2708</u>
35	35
37	37
38	38
39	39, 3901, 3902, *3905, 3913
<u>3901</u>	<u>3901, 39</u>
<u>3902</u>	<u>3902, 39</u>
<u>3905</u>	<u>3905, 39</u>
<u>3913</u>	<u>3913, 39</u>
40	40, 64
<u>4001</u>	<u>4001, 60</u>
<u>4002</u>	<u>4002, 61</u>
<u>4005</u>	<u>4005, 50</u>
<u>4006</u>	<u>4006, 61</u>
41	41
42	42
44	44, 4402, 4403

Patient B Locus Antigen	Equivalent Donor Antigens
<u>4402</u>	<u>4402, 44</u>
<u>4403</u>	<u>4403, 44</u>
<u>4415</u>	<u>4415, 45</u>
45	45, 4415
46	46
47	47
48	48
49	49
50	50, 4005
51	51, 5101, 5102, 5103
<u>5101</u>	<u>5101, 51</u>
<u>5102</u>	<u>5102, 51</u>
52	52
53	53
54	54
55	55
56	56
57	57, 5701, 5703
<u>5701</u>	<u>5701, 57</u>
<u>5703</u>	<u>5703, 57</u>
58	58
59	59
60	60, 4001

Patient B Locus Antigen	Equivalent Donor Antigens
61	61, <u>4002</u> , <u>4006</u>
62	62, <u>1501</u>
63	63, <u>1516</u> , <u>1517</u>
64	64, <u>1401</u>
65	65, <u>1402</u>
67	67
70	70, <u>71</u> , <u>72</u>
71	71, <u>70</u> , <u>1510</u>
72	72, <u>70</u> , <u>1503</u>
73	73

Patient B Locus Antigen	Equivalent Donor Antigens
75	75, <u>1502</u> , <u>1511</u> <del>15</del>
76	76, <del>15</del> , <u>1512</u>
77	77, <del>15</del> , <u>1513</u>
78	78
81	81
82	82, *8201
<del>703</del>	<del>703</del> , 7
*0804	*0804, 8
*1304	*1304, 15, 21, 49, 50
<del>2708</del>	<del>2708</del> , 27

Patient B Locus Antigen	Equivalent Donor Antigens
<del>3901</del>	<del>3901</del> , 39
<del>3902</del>	<del>3902</del> , 39
*3905	*3905, 39
4005	4005, 50
5101	5101, 51
5102	5102, 51, 53
5103	5103, 51
7801	7801
*8201	*8201, 82
** 99	(No equivalent)



**Table 4-54: HLA DR Matching Antigen Equivalence**

Patient DR Locus Antigen	Equivalent Donor Antigens
1	1, <del>103</del> , <u>0101</u> , <u>0102</u>
<u>0101</u>	<u>0101</u> , 1
<u>0102</u>	<u>0102</u> , 1
<u>103</u>	<u>103</u>
2	2
3	3
<u>0301</u>	<u>0301</u> , 17
<u>0302</u>	<u>0302</u> , 18
4	4
<u>0401</u>	<u>0401</u> , 4
<u>0402</u>	<u>0402</u> , 4
<u>0403</u>	<u>0403</u> , 4
<u>0404</u>	<u>0404</u> , 4
<u>0405</u>	<u>0405</u> , 4
<u>0407</u>	<u>0407</u> , 4
5	5
6	6
7	7
8	8
9	9
<u>0901</u>	<u>0901</u> , 9
<u>0902</u>	<u>0902</u> , 9
10	10
11	11
<u>1101</u>	<u>1101</u> , 11
<u>1104</u>	<u>1104</u> , 11
12	12
<u>1201</u>	<u>1201</u> , 12
<u>1202</u>	<u>1202</u> , 12
13	13, 1301, 1303
<u>1301</u>	<u>1301</u> , 13
<u>1303</u>	<u>1303</u> , 13
14	14, 1401, 1402, 1403, 1404, 1454
<u>1401</u>	<u>1401</u> , 14, 1454
<u>1402</u>	<u>1402</u> , 14
<u>1403</u>	<u>1403</u> , 14
<u>1404</u>	<u>1404</u> , 14

Patient DR Locus Antigen	Equivalent Donor Antigens
<u>1454</u>	<u>1454</u> , 14, <u>1401</u>
15	15
<u>1501</u>	<u>1501</u> , 15
<u>1502</u>	<u>1502</u> , 15
<u>1503</u>	<u>1503</u> , 15
16	16
<u>1601</u>	<u>1601</u> , 16
<u>1602</u>	<u>1602</u> , 16
17	17, <u>0301</u>
18	18, <u>0302</u>
103	103, 1
1403	1403, 14, 6
1404	1404, 14, 6
<del>** 99</del>	(No equivalent)

\* Indicates an allele; may not have a WHO-approved serologic specificity

\*\* Code 99 means not tested

Examples of how “Matching Antigen Equivalences” works:

- If the patient candidate types as has B70: only donors that type as with B70, B71, and B72 are considered not mismatched.
- If the patient candidate types as has B71: only donors that type as with B71 or B1510 and B720 are considered not mismatched. Donors with B72 are considered mismatched.

Tables 4-5, 4-6, 4-7, 4-8, 4-9, 4-10, 4-11 and 4-12, show candidate-donor unacceptable antigen combinations. For each candidate antigen, the donor antigens that are unacceptable are listed below.

**Table 4-65: HLA A Unacceptable Antigen Equivalences**

Patient Unacceptable A Locus Antigen	Donor Equivalent Antigen
1	1
2	2, 0201, 0202, 0203, 0205, 0206, 240
0201	0201
0202	0202
0203	0203
0205	0205
0206	0206
3	3
9	9, 23, 24, 2402, 2403
10	10, 25, 26, 34, 3401, 3402, 66, *6601, *6602, 43
11	11, 1101, 1102
1101	1101
1102	1102

Patient Unacceptable A Locus Antigen	Donor Equivalent Antigen
19	19, 29, 2901, 2902, 30, 3001, 3002, 31, 32, 33, 3301, 3303, 74
23	23
24	24, 2402, 2403
2402	2402
2403	2403
25	25
26	26
28	28, 68, 69, 6801, 6802
29	29, 2901, 2902
2901	2901
2902	2902
30	30, 3001, 3002
3001	3001
3002	3002
31	31
32	32

Patient Unacceptable A Locus Antigen	Donor Equivalent Antigen
33	33, 3301, 3303
3301	3301
3303	3303
34	34, 3401, 3402
3401	3401
3402	3402
36	36
43	43
66	66, *6601, *6602
6601	6601
6602	6602
68	68, 6801, 6802
6801	6801
6802	6802
69	69
74	74
80	80
203	203
240	240
2403	2403
*6601	*6601
*6602	*6602

**Table 4-76 HLA B Unacceptable Antigen Equivalences**

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
5	5, 51, <u>5101</u> , <u>5102</u> , <del>5403</del> , <del>52</del> , <del>78</del>
7	7, <del>703</del> , <u>0702</u>
<u>0702</u>	<u>0702</u>
8	8
<u>0802</u>	<u>0802</u>
<u>0803</u>	<u>0803</u>
<u>0804</u>	<u>0804</u>
12	12, 44, <u>4402</u> , <u>4403</u> , <u>4415</u> , 45
13	13, <u>1301</u> , <u>1302</u>
<u>1301</u>	<u>1301</u>
<u>1302</u>	<u>1302</u>
14	14, 64, 65, <u>1401</u> , <u>1402</u>
<u>1401</u>	<u>1401</u>
<u>1402</u>	<u>1402</u>
15	15, 62, 63, 75, 76, 77, <u>1501</u> , <u>1502</u> , <u>1503</u> , <u>1510</u> , <u>1511</u> , <u>1512</u> , <u>1513</u> , <u>1516</u> , <u>1517</u>
<u>1501</u>	<u>1501</u>
<u>1502</u>	<u>1502</u>
<u>1503</u>	<u>1503</u>
<u>1510</u>	<u>1510</u>
<u>1511</u>	<u>1511</u>
<u>1512</u>	<u>1512</u>
<u>1513</u>	<u>1513</u>
<u>1516</u>	<u>1516</u>
<u>1517</u>	<u>1517</u>
16	16, 38, 39, <u>3901</u> , <u>3902</u> , <u>3905</u> , <u>3913</u>

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
17	17, 57, <u>5701</u> , <u>5703</u> , 58
18	18
21	21, 49, 50, 4005
22	22, 54, 55, 56
27	27, <u>2705</u> , <u>2708</u>
<u>2705</u>	<u>2705</u>
<u>2708</u>	<u>2708</u>
35	35
37	37
38	38
39	39, 3901, 3902, *3905, <u>3913</u>
<u>3901</u>	<u>3901</u>
<u>3902</u>	<u>3902</u>
<u>3905</u>	<u>3905</u>
<u>3913</u>	<u>3913</u>
40	40, 60, 61, <u>4001</u> , <u>4002</u>
<u>4001</u>	<u>4001</u> , 60
<u>4002</u>	<u>4002</u>
<u>4005</u>	<u>4005</u> , 50
<u>4006</u>	<u>4006</u>
41	41
42	42
44	44, <u>4402</u> , <u>4403</u>
<u>4402</u>	<u>4402</u>
<u>4403</u>	<u>4403</u>
<u>4415</u>	<u>4415</u> , 45
45	45, <u>4415</u>
46	46
47	47
48	48

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
49	49
50	50, 4005
51	51, <u>5101</u> , <u>5102</u> - <u>5103</u>
<u>5101</u>	<u>5101</u>
<u>5102</u>	<u>5102</u>
52	52
53	53
54	54
55	55
56	56
57	57, <u>5701</u> , <u>5703</u>
<u>5701</u>	<u>5701</u>
<u>5703</u>	<u>5703</u>
58	58
59	59
60	60
61	61, <u>4002</u> , <u>4006</u>
62	62, <u>1501</u>
63	63, <u>1516</u>
64	64, <u>1401</u>
65	65, <u>1402</u>
67	67
70	70, 71, 72, <u>1503</u> , <u>1510</u>
71	71, <u>1510</u>
72	72, <u>1503</u>
73	73
75	75, <u>1502</u> , <u>1511</u>
76	76, <u>1512</u>
77	77, <u>1513</u>
78	78
81	81
82	82, *8204
703	703
*0804	*0804

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
*1304	*1304
2708	2708
3904	3904
3902	3902
*3905	*3905
4005	4005, 50
5102	5102
5103	5103
7804	7804, 78
*8204	*8204, 82

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
Bw4	Bw4, <u>0802</u> , <u>0803</u> , <u>0804</u> , 5, 13, <u>1301</u> , <u>1302</u> , <u>1513</u> , <u>1516</u> , <u>1517</u> , 17, 27, 37, 38, 44, <u>4402</u> , <u>4403</u> , <u>4415</u> , 47, 49, 51, <u>5101</u> , <u>5102</u> , 52, 53, 57, <u>5701</u> , <u>5703</u> , 58, 59, 63, 77

Patient Unacceptable B Locus Antigen	Donor Equivalent Antigens
Bw6	Bw6, 7, <u>0702</u> , 8, <u>0801</u> , 14, <u>1401</u> , <u>1402</u> , <u>1501</u> , <u>1502</u> , <u>1503</u> , <u>1510</u> , <u>1511</u> , <u>1512</u> , 18, 22, 2708, 35, 39, <u>3901</u> , <u>3902</u> , <u>3905</u> , <u>3913</u> , 40, <u>4001</u> , <u>4002</u> , <u>4006</u> , 41, 42, 45, 48, 50, *4005, 54, 55, 56, 60, 61, 62, 64, 65, 67, 70, 71, 72, 75, 76, 78, 81, 82

**Table 4-87: HLA C Unacceptable Antigen Equivalences**

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigens
w <u>01</u>	w <u>01</u>
w <u>02</u>	w <u>02</u>
w <u>03</u>	w <u>03</u> , w <u>09</u> , w <u>10</u>
w <u>04</u>	w <u>04</u>
w <u>05</u>	w <u>05</u>
w <u>06</u>	w <u>06</u>

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigens
w <u>07</u>	w <u>07</u> , <u>0701</u> , <u>0702</u>
<u>0701</u>	<u>0701</u>
<u>0702</u>	<u>0702</u>
w <u>08</u>	w <u>08</u>
w <u>09</u>	w <u>09</u>
w <u>10</u>	w <u>10</u>

Patient Unacceptable C Locus Antigen	Donor Equivalent Antigens
* <u>12</u>	* <u>12</u>
* <u>14</u>	* <u>14</u>
* <u>15</u>	* <u>15</u>
* <u>16</u>	* <u>16</u>
* <u>17</u>	* <u>17</u>
* <u>18</u>	* <u>18</u>

**Table 4-98: HLA DR Unacceptable Antigen Equivalences**

Patient Unacceptable DR Locus Antigen	Donor Equivalent Antigens
1	1, <u>0101</u> , <u>0102</u>
<u>0101</u>	<u>0101</u>
<u>0102</u>	<u>0102</u>
<u>103</u>	<u>103</u>
2	2, 15, <u>1501</u> , <u>1502</u> , <u>1503</u> , 16, <u>1601</u> , <u>1602</u>
3	3, 17, 18, <u>0301</u> , <u>0302</u>
<u>0301</u>	<u>0301</u> , 17
<u>0302</u>	<u>0302</u> , 18
4	4, <u>0401</u> , <u>0402</u> , <u>0403</u> , <u>0404</u> , <u>0405</u> , <u>0407</u>
<u>0401</u>	<u>0401</u>
<u>0402</u>	<u>0402</u>
<u>0403</u>	<u>0403</u>
<u>0404</u>	<u>0404</u>
<u>0405</u>	<u>0405</u>
<u>0407</u>	<u>0407</u>
5	5, 11, <u>1101</u> , <u>1104</u> , 12, <u>1201</u> , <u>1202</u>
6	6, 13, <u>1301</u> , <u>1303</u> , 14, <u>1401</u> , <u>1402</u> , 1403, 1404, <u>1454</u>
7	7
8	8
9	9, <u>0901</u> , <u>0902</u>
<u>0901</u>	<u>0901</u>
<u>0902</u>	<u>0902</u>
10	10
11	11, <u>1101</u> , <u>1104</u>
<u>1101</u>	<u>1101</u>

Patient Unacceptable DR Locus Antigen	Donor Equivalent Antigens
<u>1104</u>	<u>1104</u>
12	12, <u>1201</u> , <u>1202</u>
<u>1201</u>	<u>1201</u>
<u>1202</u>	<u>1202</u>
13	13, <u>1301</u> , <u>1303</u>
<u>1301</u>	<u>1301</u>
<u>1303</u>	<u>1303</u>
14	14, <u>1401</u> , <u>1402</u> , <u>1403</u> , 1404, <u>1454</u>
<u>1401</u>	<u>1401</u>
<u>1402</u>	<u>1402</u>
<u>1403</u>	<u>1403</u>
<u>1404</u>	<u>1404</u>
<u>1454</u>	<u>1454</u>
15	15, <u>1501</u> , <u>1502</u> , <u>1503</u>
<u>1501</u>	<u>1501</u>
<u>1502</u>	<u>1502</u>
<u>1503</u>	<u>1503</u>
16	16, <u>1601</u> , <u>1602</u>
<u>1601</u>	<u>1601</u>
<u>1602</u>	<u>1602</u>
17	17, <u>0301</u>
18	18, <u>0302</u>
403	403
4403	4403
4404	4404
51*	51
52*	52
53*	53

**Table 4-9: HLA DR51 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DR51 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>5*01:01</u>	<u>5*01:01</u>
<u>5*02:02</u>	<u>5*02:02</u>
<u>51</u>	<u>51, 5*01:01, 5*02:02</u>

**Table 4-10: HLA DR52 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DR52 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>3*01:01</u>	<u>3*01:01</u>
<u>3*02:02</u>	<u>3*02:02</u>
<u>3*03:01</u>	<u>3*03:01</u>
<u>52</u>	<u>52, 3*01:01, 3*02:02, 3*03:01</u>

**Table 4-11: HLA DR53 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DR 53 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>4*01:01</u>	<u>4*01:01</u>
<u>4*01:03</u>	<u>4*01:03</u>
<u>53</u>	<u>53, 4*01:01, 4*01:03</u>

**Table 4-102: HLA DQB1 Unacceptable Antigen Equivalences**

<u>Patient Unacceptable DQB1 Locus Antigen</u>	<u>Donor Equivalent Antigens</u>
<u>1</u>	<u>1, 5, 6, 0501, 0502, 0601, 0602, 0603, 0604, 0609</u>
<u>2</u>	<u>2, 0201, 0202</u>
<u>3</u>	<u>3, 7, 8, 9, 0301, 0302, 0303, 0319</u>
<u>0301</u>	<u>0301, 7</u>
<u>0302</u>	<u>0302, 8</u>
<u>0303</u>	<u>0303, 9</u>
<u>0319</u>	<u>0319, 7</u>
<u>4</u>	<u>4, 0401, 0402</u>
<u>0401</u>	<u>0401</u>
<u>0402</u>	<u>0402</u>
<u>5</u>	<u>5, 0501, 0502, 4</u>
<u>0501</u>	<u>0501</u>
<u>0502</u>	<u>0502</u>
<u>6</u>	<u>6, 4, 0601, 0602, 0603, 0604, 0609</u>
<u>0601</u>	<u>0601</u>
<u>0602</u>	<u>0602</u>
<u>0603</u>	<u>0603</u>
<u>0604</u>	<u>0604</u>

Patient Unacceptable DQB1 Locus Antigen	Donor Equivalent Antigens
<u>0609</u>	<u>0609</u>
7	7, 3, <u>0301, 0319</u>
8	8, 3, <u>0302</u>
9	9, 3, <u>0303</u>

\* ~~Indicates an allele; may not have a WHO-approved serologic specificity~~

~~\*\*\* Please refer to the end of this section for information~~

Examples of how “Unacceptable Antigen Equivalences” works:

If a ~~patient candidate~~ has B70 listed as an “unacceptable antigen”, donors typed as B70, B71, ~~and or~~ B72, 1503, or 1510 are considered unacceptable. ~~Donors typed as B73 and B75 are considered acceptable.~~

**Table 4-13: Additional Unacceptable Antigen Equivalences to be used in the Calculated Panel Reactive Antibody (CPRA) Only**

Locus	Patient Unacceptable Antigen	Unacceptable DR antigen equivalences used for CPRA calculation
<u>DR51</u>	<u>5*0101</u>	<u>2, 15, 16</u>
	<u>5*0202</u>	<u>2, 15, 16</u>
	<u>51</u>	<u>2, 15, 16</u>
<u>DR52</u>	<u>3*0101</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
	<u>3*0202</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
	<u>3*0301</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
	<u>52</u>	<u>3, 5, 6, 11, 12, 13, 14, 17, 18</u>
<u>DR53</u>	<u>4*0101</u>	<u>4, 7, 9</u>
	<u>4*0103</u>	<u>4, 7, 9</u>
	<u>53</u>	<u>4, 7, 9</u>

**Additional Unacceptable Antigen Equivalences to be used in the Calculated PRA Only:**

~~DR51 should also include DR2, DR15, DR16.~~

~~DR52 should also include DR3, DR5, DR6, DR11, DR12, DR13, DR14, DR17, DR18.~~

~~DR53 should also include DR4, DR7, DR9.~~

## 13.5 OPTN KPD Histocompatibility Testing

### 13.5.A HLA Typing Requirements for OPTN KPD Candidates

Before a candidate can appear on an OPTN KPD match run, the paired candidate’s transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A

- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-DR

If the candidate has unacceptable antigens listed for any of the following HLA types, then the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for the corresponding HLA type before the candidate can appear on an OPTN KPD match run:

- HLA-C
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DPB1
- HLA-DQA1
- HLA-DQB1

### **13.5.CHLA Typing Requirements for OPTN KPD Donors**

Before a donor can appear on an OPTN KPD match run, the donor's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DPB1
- HLA-DQA1
- HLA-DQB1

#



# ***Effective Date Change - Modifications to the Imminent and Eligible Neurological Death Data Reporting Definitions***

**Sponsoring Committee:** Organ Procurement Organization (OPO)

**Policy/Bylaws Affected:** 1.2: Eligible Death and Imminent Neurological Death Definitions

**Public Comment:** September 2012

**Effective Date:** January 1, 2017

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## **Problem Statement**

The OPTN/UNOS Board of Directors approved changes to the Imminent and Eligible Death Neurological Data Definitions during its June 2013 meeting and set an effective date of December 1, 2013. However, implementing these policy changes would result in OPOs having to report two separate sets of imminent and eligible neurological death data because of differences in the OPTN and Centers for Medicare & Medicaid Services (CMS) reporting definitions. The Committee has delayed the effective date twice in order to allow CMS time to make corresponding regulatory changes. The Committee has actively engaged HRSA and CMS in an effort to move this policy change forward; however, with no guarantee of a regulation change before the end of 2015, the Committee voted unanimously to delay the effective date until January 1, 2017.

## **Summary of Changes**

The effective date has been changed from January 1, 2016, to January 1, 2017. As a result, OPOs will not be required to report separate sets of imminent and eligible neurological death data to accommodate two different sets of definitions.

## **What Members Need to Do**

OPO staff must review these policy changes and, once implemented, apply the new definitions when reporting imminent and eligible death data on the Death Notification Registration form.

Please note that the imminent and eligible definitions are “reporting” definitions only. They are not intended to be inclusive of all actual donors; therefore, they should not be used for screening donors, or affect allocation or acceptance of organs. These criteria are not used to exclude potential organ donors and do not prevent an OPO from pursuing a donor candidate that is not classified as an eligible death.

## **Affected Policy/Bylaw Language:**

### **1.2 Definitions**

#### **Eligible death**

For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation is defined as the death of a patient who meets all the following characteristics:

- Is 75 years old or less
- Is legally declared dead by neurologic criteria according to the current standards of accepted medical

practice and state or local law

- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m<sup>2</sup> or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
  - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Greater than 70 years old
    - Age 50-69 years with history of type 1 diabetes for more than 20 years
    - Polycystic kidney disease
    - Glomerulosclerosis greater than or equal to 20% by kidney biopsy
    - Terminal serum creatinine greater than 4.0 mg/dL
    - Chronic renal failure
    - No urine output for 24 hours or longer
  - The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Cirrhosis
    - Terminal total bilirubin greater than or equal to 4 mg/dL
    - Portal hypertension
    - Macrosteatosis greater than or equal to 50%
    - Fibrosis greater than or equal to stage II
    - Fulminant hepatic failure
    - Terminal AST/ALT greater than 700 U/L
  - The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - 60 years old or older
    - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
    - History of coronary artery bypass graft (CABG)
    - History of coronary stent/intervention
    - Current or past medical history of myocardial infarction (MI)
    - Severe vessel diagnosis as supported by cardiac catheterization
    - Acute myocarditis or endocarditis, or both
    - Heart failure due to cardiomyopathy
    - Internal defibrillator or pacemaker
    - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
    - Serial echo results showing severe global hypokinesis
    - Myxoma
    - Congenital defects (surgically corrected or not)
  - The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
    - Age 65 years or older
    - Diagnosed with COPD
    - Terminal PaO<sub>2</sub>/FiO<sub>2</sub> less than 250 mmHg
    - Asthma (with daily prescription)
    - Asthma is the cause of death
    - Pulmonary fibrosis
    - Previous lobectomy
    - Multiple blebs documented on computed axial tomography (CAT) scan
    - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
    - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an eligible death unless the donor meets any of the following criteria:

- The donor has no suitable organ for transplant (as defined above)
- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits any of the following:
  - Active infections (with a specific diagnosis)
  - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
  - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus (mononucleosis), West Nile virus infection, SARS
  - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
  - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (plasmodium sp.)
  - Prion: Creutzfeldt-Jacob disease
  - General [Exclusions to the Definition of Eligible]: aplastic anemia, agranulocytosis
  - Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
  - Previous malignant neoplasms with current evident metastatic disease
  - A history of melanoma
  - Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
  - Active fungal or parasitic meningitis or encephalitis
  - No discernible cause of death

#### **Imminent neurological death**

Imminent Neurological Death is defined as the death of a patient who meets both of the following criteria:

- Meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria according to current standards of accepted medical practice and state or local law.
- Has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and is lacking at least two of the additional brain stem reflexes that follow:
  - Pupillary reaction
  - Response to iced caloric
  - Gag Reflex
  - Cough Reflex
  - Corneal Reflex
  - Doll's eyes reflex
  - Response to painful stimuli

A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurological death.

# ***Revising Kidney Paired Donation Pilot Program Priority Points***

**Sponsoring Committee:** Kidney Transplantation

**Policy/Bylaws Affected:** Policies 1.2: Definitions, 13.7: OPTN KPD Screening Criteria, 13.8: Two- and Three-Way Matches, and 13.9: Donor Chains

**Public Comment:** August 2015

**Effective Date:** Pending programming and notice to OPTN membership

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## **Problem Statement**

The Kidney Paired Donation Pilot Program (OPTN KPD) system does not fully account for how difficult it is to match some pairs because of high calculated panel reactive antibody (CPRA) or blood types (i.e. pairs with blood type O candidates and non-O donors). Additionally, KPD informed consent policy requires that transplant hospitals inform KPD candidates and donors of a remedy for a failed exchange (if one exists). A failed exchange happens when a KPD candidate does not receive a transplant after their paired donor has donated. Existing OPTN policy did not provide a specific remedy for failed exchanges within the OPTN KPD system.

## **Summary of Changes**

The policy revisions change how the OPTN KPD system optimizes its pair pool. It does this by revising the priority points table by adding points for donor and candidate blood type and adopting a sliding scale for CPRA points. Policy changes also provide a remedy for OPTN KPD candidates that are part of a failed exchange. Policy now refers to these candidates as “orphan candidates.” Orphan candidates will receive 1,000,000 priority points only if the candidate was a part of the OPTN KPD failed exchange. Candidates in failed exchanges in other KPD programs will not receive orphan candidate status in the OPTN KPD. Other policy changes also clarify certain operational aspects of the OPTN KPD program such as describing how chains continue through bridge donation and logistical requirements for two- and three- way matches. All changes are specific to the OPTN KPD program and do not apply to any other KPD programs.

## **What Members Need to Do**

You will not be required to collect any additional data. As required by Policy 13.3: Informed Consent for KPD Candidates and Policy 13.4: Informed Consent for KPD Donors, anyone participating in the OPTN KPD program will need to learn the changes outlined in the proposal so that you may inform your candidates and donors appropriately. The proposed language will not change the current way UNOS conducts routine site surveys. Any data entered in UNet<sup>SM</sup> may be subject to OPTN review, and you are required to provide documentation if requested.

## **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## 1.2 Definitions

### Bridge donor

A Kidney Paired Donation (KPD) donor who does not have a match identified during the same match run as the donor's paired candidate and continues a chain in a future match run.

### Chain

A set of KPD matches that begins with a donation from a non-directed living donor to that KPD donor's matched candidate. This candidate's paired living donor then donates to the KPD donor's matched candidate. A chain continues until a living donor donates to an orphan candidate, a waiting list candidate, or is a bridge donor.

### Orphan candidate

A KPD candidate who does not receive a kidney transplant from the matched donor for any reason after the candidate's paired donor has donated.

## 13.7 OPTN KPD Screening Criteria

### 13.7.F OPTN KPD Prioritization Points

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

**Table 13-2: OPTN KPD Prioritization Points**

If the:	Then the match will receive:
<u>Candidate is registered for the OPTN KPD program</u>	<u>.07 points for each day according to Policy 13.7.G: OPTN KPD Waiting Time Reinstatement</u>
Candidate is a 0-ABDR mismatch with the potential donor	<del>200</del> 10 points
<del>Candidate and potential donor are registered for the OPTN KPD program in the same region</del>	25 points
<del>Candidate and potential donor are registered for the OPTN KPD program in the same DSA</del>	25 points
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	2575 points
<u>Candidate and potential donor had a previous crossmatch that was one of the following:</u> <ul style="list-style-type: none"> <li>• <u>Negative</u></li> <li>• <u>Positive and acceptable with desensitization</u></li> <li>• <u>Positive and acceptable without desensitization</u></li> </ul>	75 points

If the:	Then the match will receive:
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate is a prior living organ donor	150 points
Candidate ABO is O	100 points
Candidate ABO is B	50 points
Candidate ABO is A	25 points
Candidate ABO is AB	0 points
Paired donor ABO is O	0 points
Paired donor ABO is B	100 points
Paired donor ABO is A	250 points
Paired donor ABO is AB	500 points
Candidate has a CPRA greater than or equal to 80%	125 points
Candidate CPRA is 0-19	0 points
Candidate CPRA is 20-29	5 points
Candidate CPRA is 30-39	10 points
Candidate CPRA is 40-49	15 points
Candidate CPRA is 50-59	20 points
Candidate CPRA is 60-69	25 points
Candidate CPRA is 70-74	50 points
Candidate CPRA is 75-79	75 points
Candidate CPRA is 80-84	125 points
Candidate CPRA is 85-89	200 points
Candidate CPRA is 90-94	300 points
Candidate CPRA is 95	500 points
Candidate CPRA is 96	700 points
Candidate CPRA is 97	900 points
Candidate CPRA is 98	1250 points
Candidate CPRA is 99	1500 points
Candidate CPRA is 100	2000 points
Potential donor has at least one of the other antibody specificities reported for the candidate	-5 points
Candidate is an orphan candidate	1,000,000 points

### 13.7.G OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program with another living donor. Immediate and permanent non-function of a transplanted kidney is defined as either:

1. Kidney graft removal within the first 90 days of transplant documented by a report of the removal of the transplanted kidney.
2. Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days of the kidney transplant.

KPD waiting time will be reinstated when the OPTN Contractor receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

### **13.7.H Priority for Orphan Candidates**

A candidate will be eligible for orphan candidate priority only if the candidate qualified for orphan status through participation in the OPTN KPD program. An orphan candidate will receive priority according to Table 13-2: OPTN KPD Prioritization Points, even if the candidate has another willing living donor. The orphan candidate will retain this priority until the orphan candidate receives a kidney transplant. The orphan candidate can always refuse a match offer and retain orphan candidate priority.

## **13.8 Two- and Three-Way Matches**

### **13.8.B Logistical Requirements for Two- and Three-Way Matches**

In two-way or three-way exchanges in the OPTN KPD program, all KPD donor surgeries involved in the exchange must begin within 24 hours and only after all donor surgeons involved in the exchange agree to proceed. Each matched donor recovery must be scheduled to begin within 24 hours of the start of the previous matched donor recovery. The donor surgeries in the exchange will begin only after all transplant programs agree to proceed.

## **13.9 Donor Chains**

### **13.9.B Logistical Requirements for Donor Chains**

In KPD donor chains in the OPTN KPD program, surgeries may or may not occur simultaneously. A KPD candidate must receive a kidney within 24 hours of the same day his paired KPD donor donates. A KPD candidate-donor pair will always have the option to have surgery on the same day. KPD donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a KPD candidate on the deceased donor waiting list at the transplant hospital that entered the non-directed donor that started that chain or with a KPD bridge donor who will be included in a later match run. The transplant hospital that enters the NDD can choose whether the chain can end with a bridge donor or a donation to the deceased donor waitlist. The transplant hospital registering the potential KPD donor may refuse to allow the potential KPD donor to serve as a bridge donor at any point in the process.

In OPTN KPD chains, each matched donor recovery must be scheduled to begin within 21 days from the date the matched donor's paired candidate receives a transplant. However, a KPD candidate-donor pair has the option to either have their surgeries begin within 24 hours of one another or refuse the match. Surgeries occurring within 24 hours would follow the same requirements as the two-way or three-way exchange according to Policy 13.8.B: Logistical Requirements for Two- and Three-Way Matches.

**13.9.C ~~What to Do When A Chain Breaks~~ Ending Chains**

Transplant hospitals participating in OPTN KPD must follow the requirements for ending a chain according to Table 13-3 below.



**Table 13-3: Logistical Requirements for Ending Chains**

<u>If a chain begins that:</u>	<u>Then:</u>
<p><u>Does not include a match for an orphan candidate</u></p>	<p>The transplant hospital that entered the non-directed donor (NDD) can choose to <i>either</i>:</p> <ul style="list-style-type: none"> <li>• <u>Allow the chain to continue through bridge donation, if the last paired donor in the chain is willing to be a bridge donor.</u></li> <li>• <u>End the chain with a donation from the last paired donor in the chain to a candidate on the deceased donor waiting list at the transplant hospital that entered the NDD that started the chain.</u></li> </ul>
<p><u>Includes a match for an orphan candidate</u></p>	<p><u>The chain must end with a donation to the orphan candidate.</u></p>

If the transplant hospital that entered the non-directed donor initially chooses to allow the chain to continue through bridge donation, the chain will extend until the transplant hospital reports to the OPTN Contractor that *one* of the following events has occurred:

- The bridge donor declines to donate
- The bridge donor donates to an orphan candidate
- The bridge donor donates to the deceased donor waitlist
- The transplant hospital that registered the bridge donor in the OPTN KPD program refuses to allow the donor to serve as a bridge donor

A transplant hospital that entered the non-directed donor can also request to end the chain with a donation to the deceased donor waiting list.

**13.9.CD What to Do When a Chain Breaks**

In the OPTN KPD program, a donor chain will proceed until a KPD candidate or ~~KPD potential matched~~ donor refuses a match offer.

~~If a KPD candidate or potential KPD donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a KPD candidate or potential KPD donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in *Policy 13.9.B: Logistical Requirements*.~~

If a KPD candidate or matched donor in a chain refuses a match offer, then the matched donor at the end of the chain may donate to an orphan candidate, the deceased donor waiting list, or may be a bridge donor as outlined in *Policy 13.9.B: Logistical Requirements for Donor Chains and Policy 13.9.C: Ending Chains*.

#

# ***Proposal to Establish and Clarify Requirements for Domino Donors and Non-Domino Therapeutic Organ Donors***

**Sponsoring Committee:** Living Donor

**Policy Affected:** 1.2: Definitions, 6.5.F: Allocation of Domino Donor Hearts, 14.1.A: Living Donor Psychosocial Evaluation Requirements, 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals, 14.3: Informed Consent Requirements, 14.4.B: Living Donor Medical Evaluation Requirements, 14.6.B: Placement of Non-directed Living Donor Kidneys, 14.6.C: Transplant Hospital Acceptance of Living Donor Organs, 14.9: Requirements for Domino Donors and Non-Domino Therapeutic Donors, 14.9.A: Informed Consent Requirements for Domino Donors and Non-Domino Therapeutic Donors, 14.9.B: Psychosocial and Medical Evaluation Requirements for Domino Donors and Non-Domino Therapeutic Donors, 14.9.C: Recovery of Domino Donor and Non-Domino Therapeutic Donor Organs, 14.6.D: Acceptance of Domino Donor and Non-Domino Therapeutic Donor Organs, 14.9.E: Reporting and Data Submission Requirements for Domino Donors and Non-Domino Therapeutic Donors, 18.1: Data Submission Requirements

**Public Comment:** August 2015

**Effective Date:** Upon implementation and notice to OPTN members

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## **Problem Statement**

Historically, hospitals have asked the OPTN how to handle the informed consent, psychosocial and medical evaluations, and follow-up requirements for domino donors and non-domino therapeutic donors.

Most current living donor policies are not appropriate or applicable for domino donors and non-domino therapeutic organ donors. The proposed policy modification will limit the requirements for these donors to a subset of existing policies. This subset for evaluations, disclosures, and medical testing is necessary to protect the potential organ recipient, while avoiding potential impediments or complications that could result in the non-domino therapeutic donor’s native organ being wasted rather than transplanted. This proposal would establish definitions for a domino donor and a non-domino therapeutic organ donor.

## Summary of Changes

- Informed consent requirements are limited to select elements from Policy 14.3 that address confidentiality, valuable consideration and reporting some health information.
- Psychosocial evaluation requirements are limited to one element from Policy 14.1 that requires an evaluation for disease transmission as defined by the US PHS Guideline.
- Medical evaluation requirements are limited to three elements from Policy 14.4 that address an evaluation for transmissible disease, exclusion criteria, and blood type.
- Reporting requirements are limited to submitting the Living Donor Feedback and Living Donor Registration forms.

## What Members Need to Do

Hospitals will need to follow new informed consent, medical and psychosocial evaluation, and data submission requirements specific to domino donors and non-domino therapeutic donors. You will have the option to develop and follow protocols for evaluating non-domino therapeutic donors. Hospitals currently report therapeutic non-domino donors as non-directed living donors using the Living Donor Registration Form. After programming is completed, hospitals will report such individuals as therapeutic non-domino donors using the same form.

## Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

### **Policy 1.2 (Definitions)**

#### **Therapeutic donor**

An individual who has an organ removed as a component of medical treatment and who receives a replacement organ. The organ that was removed is transplanted into another person.

#### **Non-domino therapeutic donor**

An individual who has an organ removed as a component of medical treatment and whose organ is transplanted into another person. The donor does not receive a replacement organ.

#### **~~6.5.G Allocation of Domino Donor Hearts~~**

~~If a transplant program recovers the native heart of a heart-lung recipient, then the transplant program that recovers this heart may transplant it into a second candidate registered at the same transplant program.~~

~~If, however, the transplant program does not transplant the recovered, native heart into one of its candidates, then the heart will be allocated according to *Policy 6.5: Heart Allocation*~~

~~*Classifications and Rankings.* For the purposes of allocating these hearts, the DSA of allocation is the DSA where the native heart of the heart-lung transplant recipient is recovered~~

### **14.1 Psychosocial Evaluation Requirements for Living Donors**

#### **14.1.A Living Donor Psychosocial Evaluation Requirements**

~~Living donor psychosocial evaluation requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.~~

Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung or intestine donors.

The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist, or masters prepared social worker, or licensed clinical social worker. Documentation of the psychosocial evaluation must be maintained in the living donor record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as risks for poor psychosocial outcome
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the *U.S. Public Health Service (PHS) Guideline*
3. A review of the living donor's history of smoking, alcohol, and drug use, abuse, and dependency
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
5. The determination that the living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation
6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
7. An assessment of the living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
8. A review of the living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the living donor understands the potential financial implications of living donation

## **14.2 Independent Living Donor Advocate (ILDA) Requirements**

### **14.2.A ILDA Requirements for Living Donor Recovery Hospitals**

~~Living donor ILDA requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.~~

Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine or lung donors.

For any living kidney donor who is undergoing evaluation for donation, the living donor recovery hospital must designate and provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.

2. Advocate for the rights of the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate. Document that each requirement has been met.
4. Review whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
  - a. Informed consent process as described in *Policy 14.3: Informed Consent Requirements*
  - b. Evaluation process according to *Policies 14.1.A: Living Donor Psychosocial Evaluation Requirements* and *14.4.B: Living Donor Medical Evaluation Requirements*
  - c. Surgical procedure
  - d. Medical risks according to *Tables 14-1 through 14-5*
  - e. Psychosocial risks according to *Tables 14-1 through 14-5*
  - f. Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Living Kidney Donation* and *18.5.C: Submission of Living Donor Death and Organ Failure*
5. Document that each topic was reviewed

### 14.3 Informed Consent Requirements

~~Living donor informed consent requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.~~

Living donor informed consent requirements apply to living kidney, liver, pancreas, and intestine or lung donors.

The recovery hospital is responsible for informed consent which must include *all* of the components in *Tables 14-1 through 14-5*.

Documentation of informed consent must be maintained in the donor medical record.

**Table 14-1: Requirements for Living Donor Informed Consent**

The recovery hospital must:	These elements of informed consent :
<b>Obtain from living donors</b>	The donor's signature on a document that confirms that the donor: <ul style="list-style-type: none"> <li>• Is willing to donate</li> <li>• Is free from inducement and coercion and</li> <li>• Has been informed that he or she may decline to donate at any time</li> </ul>

<p>The recovery hospital must:</p>	<p>These elements of informed consent :</p>
<p><b>Provide to living donors</b></p>	<p>An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.</p> <p>The ILDA must be available to assist the donor during the consent process, according to <i>Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements</i>.</p> <p>Instruction about all phases of the living donation process, which include:</p> <ul style="list-style-type: none"> <li>• Consent</li> <li>• Medical and psychosocial evaluations</li> <li>• Pre and post-operative care</li> <li>• Required post-operative follow up according to <i>Policy 18.5: Living Donor Data Submission Requirements</i>.</li> </ul> <p>Teaching or instructional material can include any media, one-on-one or small group interaction.</p> <p>Teaching or instruction must be provided in a language in which the donor is able to engage in meaningful dialogue with recovery hospital’s staff.</p>

<p><b>The recovery hospital must:</b></p>	<p><b>These elements of informed consent :</b></p>
<p><b>Disclose to living donors</b></p>	<p>The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.</p> <p>It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations.</p> <p>The recovery hospital must provide an ILDA.</p> <p>Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that:</p> <ol style="list-style-type: none"> <li>a. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor’s evaluation or the living donor transplant occurs.</li> <li>b. Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the donor.</li> </ol> <p>Health information obtained during the evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities.</p> <p>The recovery hospital is required to:</p> <ol style="list-style-type: none"> <li>a. Report living donor follow up information, at the time intervals specified in <i>Policy 18.5: Living Donor Data Submission Requirements</i>.</li> <li>b. Have the donor commit to post operative follow up testing coordinated by the recovery hospital.</li> </ol> <p>Any infectious disease or malignancy pertinent to acute recipient care discovered during the donor’s first two years of follow up care:</p> <ol style="list-style-type: none"> <li>a. May need to be reported to local, state or federal public health authorities</li> <li>b. Will be disclosed to their recipient’s transplant center</li> <li>c. Will be reported through the OPTN Improving Patient Safety Portal</li> </ol>

The recovery hospital must:	These elements of informed consent :
<b>Disclose to living donors</b>	<p>A living donor must undergo a medical evaluation according to <i>Policy 14.4: Medical Evaluation Requirements for Living Donors</i> and a psychosocial evaluation as required by <i>Policy 14.1: Psychosocial Evaluation Requirements for Living Donors</i>.</p> <p>The hospital may refuse the donor. In such cases, the recovery hospital must inform the donor that a different recovery hospital may evaluate the donor using different selection criteria.</p> <p>The following are inherent risks associated with evaluation for living donation:</p> <ol style="list-style-type: none"> <li>a. Allergic reactions to contrast</li> <li>b. Discovery of reportable infections</li> <li>c. Discovery of serious medical conditions</li> <li>d. Discovery of adverse genetic findings unknown to the donor</li> <li>e. Discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team</li> </ol> <p>There are surgical, medical, psychosocial, and financial risks associated with living donation, which may be temporary or permanent and include, but are not limited to, <i>all</i> of the following:</p>
<b>Disclose to living donors</b>	<ol style="list-style-type: none"> <li>a. Potential medical or surgical risks: <ol style="list-style-type: none"> <li>i. Death</li> <li>ii. Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure</li> <li>iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction</li> <li>iv. That the morbidity and mortality of the donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions</li> </ol> </li> <li>b. Potential psychosocial risks: <ol style="list-style-type: none"> <li>i. Problems with body image</li> <li>ii. Post-surgery depression or anxiety</li> <li>iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies</li> <li>iv. Changes to the donor's lifestyle from donation</li> </ol> </li> <li>c. Potential financial impacts: <ol style="list-style-type: none"> <li>i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs</li> <li>ii. Need for life-long follow up at the donor's expense</li> <li>iii. Loss of employment or income</li> <li>iv. Negative impact on the ability to obtain future employment</li> <li>v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance</li> <li>vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance</li> </ol> </li> </ol>



**Table 14-2: Required Recipient Outcome and Transplanted Organ Survival Data**

If the recovery hospital and the recipient hospital:	Then:	Including <i>all</i> the following information:
Are the same	The recovery hospital must provide the living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports.	<ul style="list-style-type: none"> <li>• National 1-year patient and transplanted organ survival</li> <li>• The hospital's 1-year patient and transplanted organ survival</li> <li>• Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital</li> </ul>
Will not be the same and the recipient hospital is known	The recovery hospital must provide the living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program-specific reports.	<ul style="list-style-type: none"> <li>• National 1-year patient and transplanted organ survival</li> <li>• The recipient hospital's 1-year patient and transplanted organ survival</li> <li>• Notification about all CMS outcome requirements not being met by the recipient hospital</li> </ul>

**Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors**

The recovery program must:	These additional elements as components of informed consent for living kidney donors:
Provide to all living kidney donors	<p>Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:</p> <ol style="list-style-type: none"> <li>a. On average, living donors may have a 25-35% permanent loss of kidney function after donation.</li> <li>b. Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile.</li> <li>c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD.</li> <li>d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.</li> <li>e. Dialysis is required if the donor develops ESRD.</li> <li>f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to <i>Policy 8.3 Kidney Allocation Points</i>.</li> </ol>
Disclose to all living kidney donors	<p>Surgical risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Potential medical or surgical risks: <ul style="list-style-type: none"> <li>○ Decreased kidney function</li> <li>○ Kidney failure and the need for dialysis or kidney transplant for the donor</li> </ul> </li> </ul>

**Table 14-4: Additional Requirements for the Informed Consent of Living Liver Donors**

The recovery program must:	These additional elements as components of informed consent for living liver donors:
Disclose to all living liver donors	<p>Surgical risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Acute liver failure with need for liver transplant.</li> <li>• Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation.</li> <li>• Risk of red cell transfusions or other blood products.</li> <li>• Biliary complications, including leak or stricture that may require additional intervention.</li> <li>• Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.</li> </ul>

**Table 14-5: Additional Required Living Liver Donor Recipient Outcome and Transplanted Living Donor Liver Survival Data**

If the recovery hospital and the recipient hospital:	Then:	Including <i>all</i> the following information:
Are the same	The recovery hospital must provide the living donor with the hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.	The hospital's 1-year living donor recipient's survival and recipient's graft survival rates
Will not be the same and the recipient hospital is known	The recovery hospital must provide the living donor with the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	The recipient hospital's 1-year living donor recipient's survival and graft survival rates

### 14.4.A Living Donor Medical Evaluation Requirements

~~Living donor medical evaluation requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.~~

Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or intestine donors.

A medical evaluation of the living donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Tables 14-6 through 14-9* below.

**Table 14-6: Requirements for Living Donor Medical Evaluations**

<b>This evaluation must be completed:</b>	<b>Including evaluation for and assessment of this information:</b>
<b>General donor history</b>	<ol style="list-style-type: none"> <li>1. A personal history of significant medical conditions which include but are not limited to:               <ol style="list-style-type: none"> <li>a. Hypertension</li> <li>b. Diabetes</li> <li>c. Lung disease</li> <li>d. Heart disease</li> <li>e. Gastrointestinal disease</li> <li>f. Autoimmune disease</li> <li>g. Neurologic disease</li> <li>h. Genitourinary disease</li> <li>i. Hematologic disorders</li> <li>j. Bleeding or clotting disorders</li> <li>k. History of cancer including melanoma</li> </ol> </li> <li>2. History of infections</li> <li>3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication</li> <li>4. Allergies</li> <li>5. An evaluation for coronary artery disease</li> </ol>
<b>General family history</b>	<ul style="list-style-type: none"> <li>• Coronary artery disease</li> <li>• Cancer</li> </ul>
<b>Social history</b>	<ul style="list-style-type: none"> <li>• Occupation</li> <li>• Employment status</li> <li>• Health insurance status</li> <li>• Living arrangements</li> <li>• Social support</li> <li>• Smoking, alcohol and drug use and abuse</li> <li>• Psychiatric illness, depression, suicide attempts</li> <li>• Increased risk behavior as defined by the <i>U.S. Public Health Services (PHS) Guideline</i></li> </ul>
<b>Physical Exam</b>	<ul style="list-style-type: none"> <li>• Height</li> <li>• Weight</li> <li>• BMI</li> <li>• Vital signs</li> <li>• Examination of all major organ systems</li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>General laboratory and imaging tests</b>	<ul style="list-style-type: none"> <li>• Complete blood count (CBC) with platelet count</li> <li>• Blood type and subtype as specified in <i>14.5: Living Donor Blood Type Determination and Reporting</i> and its subsections</li> <li>• Prothrombin Time (PT) or International Normalized Ratio (INR)</li> <li>• Partial Thromboplastin Time (PTT)</li> <li>• Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)</li> <li>• HCG quantitative pregnancy test for premenopausal women without surgical sterilization</li> <li>• Chest X-Ray</li> <li>• Electrocardiogram (ECG)</li> </ul>
<b>Transmissible disease screening</b>	<p>Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> <li>1. CMV (Cytomegalovirus) antibody</li> <li>2. EBV (Epstein Barr Virus) antibody</li> <li>3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery</li> <li>4. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery</li> <li>5. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery</li> <li>6. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery</li> <li>7. Syphilis testing</li> </ol> <p>If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the <i>U.S. Public Health Services (PHS) Guideline</i>, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the <i>U.S. Public Health Services (PHS) Guideline</i>.</p> <p>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using <i>either</i>:</p> <ul style="list-style-type: none"> <li>• Intradermal PPD</li> <li>• Interferon Gamma Release Assay (IGRA)</li> </ul>
<b>Endemic transmissible diseases</b>	<p>Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.</p>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Cancer screening</b>	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: <ul style="list-style-type: none"> <li>• Cervical cancer</li> <li>• Breast cancer</li> <li>• Prostate cancer</li> <li>• Colon cancer</li> <li>• Lung cancer</li> </ul>

**14.6.B Placement of Non-directed Living Donor Kidneys Organs**

Prior to determining the placement of a non-directed living donor kidney organ, including non-directed organs from domino donors and non-domino therapeutic organ donors, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor kidney organ is allocated placed, the recovery hospital must document how the organ is allocated placed and the rationale for placement allocation.

This requirement does not apply to non-directed living kidney donors who donate a kidney through a Kidney Paired Donation (KPD) arrangement.

**14.6.C Transplant Hospital Acceptance of Living Donor Organs**

Transplant hospitals that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member recovery hospitals that are approved to perform living donor recovery for that organ type. If the OPTN does not have approval criteria for a living donor recovery hospital for a particular organ type, then that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals with current designated transplant program for that organ type.

A transplant hospital must only accept and transplant living donor organs according to Table 14-11 below.

**Table 14-11: Transplant Hospital Requirements for Accepting and Transplanting Living Donor Organs**

If this type of living donor organ is being recovered:	Then the recovery hospital must:
<u>Kidney</u>	<u>Meet the requirements according to the OPTN Bylaws E.5: Kidney Transplant Programs that Perform Living Donor Recovery</u>
<u>Liver</u>	<u>Meet the requirements according to the OPTN Bylaws F.6: Liver Transplant Programs that Perform Living Donor Recovery</u>
<u>Other organ types, excluding kidney or liver</u>	<u>Have current designated transplant program approval for that organ type</u>

## 14.7 Living Donor Pre-Recovery Verification

Recovery hospitals must develop and comply with a written protocol to perform pre-recovery verifications as required below.

The recovery hospital must conduct a pre-recovery verification that meets *all* of the following requirements:

1. The recovery surgeon and another licensed health care professional must participate in the verification.
2. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
3. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in *Table 14.142* below. Assistance using an OPTN approved electronic method is permitted.

**Table 14.142: Pre-Recovery Verification Requirements**

The recovery hospital must verify <i>all</i> of the following information:	Using at least <i>one</i> of these sources:
Donor ID	<ul style="list-style-type: none"> <li>• Donor identification band</li> </ul>
Organ type and laterality (if applicable)	<ul style="list-style-type: none"> <li>• OPTN computer system</li> </ul>
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	<ul style="list-style-type: none"> <li>• Donor blood type and subtype source documents</li> </ul>
Intended recipient unique identifier	<ul style="list-style-type: none"> <li>• Recipient medical record</li> <li>• OPTN computer system</li> </ul>
Intended recipient blood type	<ul style="list-style-type: none"> <li>• Recipient medical record</li> <li>• OPTN computer system</li> </ul>
Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> <li>• OPTN computer system</li> <li>• Recipient medical record</li> <li>• Attestation following verification of donor and recipient blood types</li> </ul>
Correct donor organ has been identified for the correct intended recipient	<ul style="list-style-type: none"> <li>• Donor medical record</li> <li>• OPTN computer system</li> </ul>

The recovery hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

## **14.9 Requirements for Domino Donors and Non-Domino Therapeutic Donors**

Although domino donors and non-domino therapeutic donors are considered living donors, the requirements in *Policy 14: Living Donation* are limited only to Policies 14.9 A through 14.9 E below for domino donors and non-domino therapeutic donors.

### **14.9.A Informed Consent Requirements for Domino Donors and Non-Domino Therapeutic Donors**

Recovery hospitals must obtain the donor's signature on a document that confirms that the donor:

1. Is willing to donate

2. Is free from inducement and coercion
3. Has been informed that the donor may decline to donate at any time
4. Has received information on treatment options that would not involve organ donation

Recovery hospitals must also provide all of the following disclosures to domino donors and non-domino therapeutic donors:

1. The disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient
2. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations.
3. The disclosure that health information obtained during the evaluation for donation is subject to the same regulations as all health records and could reveal conditions that must be reported to local, state, or federal public health authorities.
4. The disclosure that any new information discovered during the domino donor's or non-domino therapeutic donor's first two years of post-donation care that indicates risk of potential transmission of infectious disease or malignancy to the recipient of the domino donor's or non-domino therapeutic donor's native organ:
  - a. May need to be reported to local, state, or federal public health authorities
  - b. Will be disclosed to the recipient's transplant hospital
  - c. Will be reported through the OPTN Improving Patient Safety Portal
5. Information on treatment options that would not involve organ donation.
6. An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.

Documentation of the informed consent must be maintained in the donor medical record.

#### **14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors**

Recovery hospitals must evaluate domino donors and non-domino therapeutic donors according to all of the following requirements:

1. Perform an evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the U.S. Public Health Service (PHS) Guideline
2. Screen the domino donor or non-domino therapeutic donor for all of the following according to Policy 14.4: Medical Evaluation Requirements for Living Donors, Table 14-6: Requirements for Living Donor Medical Evaluations:
  - a. Transmissible diseases screening
  - b. Endemic transmissible diseases
  - c. Cancer screening
3. Develop and comply with written protocols for the domino donor and non-domino therapeutic donor exclusion criteria considering incorporating as appropriate the elements of Table 14-9: Living Donor Exclusion Criteria
4. Register and verify the blood type of the domino donor or non-domino therapeutic donor according to Policy 14.5: Registration and Blood Type Verification of Living Donors before Donation

Documentation of the psychosocial and medical evaluation must be maintained in the donor medical record.

**14.9.C Recovery of Domino Donor and Non-Domino Therapeutic Donor Organs**

Transplant hospitals can recover domino donor and non-domino therapeutic donor organs if the hospital has current designated transplant program approval for that organ type.

**14.9.D Acceptance of Domino Donor and Non-Domino Therapeutic Donor Organs**

Transplant hospitals must only accept domino donor and non-domino therapeutic donor organs recovered at transplant hospitals that have a current designated transplant program approval for that organ type.

**14.9.E Reporting and Data Submission Requirements for Domino Donors and Non-Domino Therapeutic Donors**

Recovery hospitals must submit the living donor feedback and living donor registration (LDR) forms for the domino donor and non-domino therapeutic donor according to *Policy 18.1: Data Submission Requirements*.

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

**18.1 Data Submission Requirements**

Members must report accurate data to the OPTN Contractor using standardized forms according to *Table 18-1* below.

**Table 18-1: Data Submission Requirements**

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory



<b><i>The following member:</i></b>	<b><i>Must submit the following materials to the OPTN Contractor:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<p><i>Either of the following:</i></p> <ul style="list-style-type: none"> <li>• 30 days after the transplant hospital removes the candidate from the waiting list because of transplant</li> <li>• 30 days after the transplant hospital submits the <i>recipient feedback</i></li> </ul>	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	<i>Death notification records (DNR)</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Host OPO	<i>Donor organ disposition (feedback)</i>	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital  This does not apply to VCA donor organs
Recovery Hospitals	<i>Living Donor Feedback</i>  Members must amend the form or contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Liver Donor Adverse Events</i>	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital  This does not apply to VCA donor organs

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital  This does not apply to VCA, <u>domino donor</u> , and <u>non-domino therapeutic donor</u> organs
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> <li>• 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure</li> <li>• 14 days from notification of the recipient's death or graft failure</li> </ul>	Each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital submits the <i>recipient feedback</i> form	Each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	24 hours after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	24 hours after the transplant	Each VCA recipient transplanted by the hospital

<b><i>The following member:</i></b>	<b><i>Must submit the following materials to the OPTN Contractor:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

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# ***Addressing the Term “Foreign Equivalent” in OPTN Bylaws***

**Sponsoring Committee:** Membership and Professional Standards

**Bylaws Affected:** OPTN Bylaws Appendices E.2: Primary Kidney Transplant Surgeon Requirements, E.2.A: Formal 2-year Transplant Fellowship Pathway, E.2.B: Clinical Experience Pathway, E.3: Primary Kidney Transplant Physician Requirements, E.3.A: Twelve-month Transplant Nephrology Fellowship Pathway, E.3.B: Clinical Experience Pathway, E.3.C: Three-year Pediatric Nephrology Fellowship Pathway, E.3.D: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway, E.3.E: Combined Pediatric Nephrology Training and Experience Pathway, E.3.G: Conditional Approval for Primary Transplant Physician, F.2: Primary Liver Transplant Surgeon Requirements, F.2.A: Formal 2-year Transplant Fellowship Pathway, F.2.B: Clinical Experience Pathway, F.3: Primary Liver Transplant Physician Requirements, F.3.B: Clinical Experience Pathway, F.3.C: Three-year Pediatric Gastroenterology Fellowship Pathway, F.3.D: Pediatric Transplant Hepatology Fellowship Pathway, F.3.E: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway, F.3.G: Conditional Approval for Primary Transplant Physician, F.4: Requirements for Director of Liver Transplant Anesthesia, F.10: Primary Intestine Transplant Surgeon Requirements, F.10.A: Full Intestine Surgeon Approval Pathway, F.10.B: Conditional Intestine Surgeon Approval Pathway, F.11: Primary Intestine Transplant Physician Requirements, F.11.B: Conditional Intestine Physician Approval Pathway, G.2: Primary Pancreas Transplant Surgeon Requirements, G.2.A: Formal 2-year Transplant Fellowship Pathway, G.2.B: Clinical Experience Pathway, G.3: Primary Pancreas Transplant Physician Requirements, G.3.B: Clinical Experience Pathway, G.3.D: Conditional Approval for Primary Transplant Physician, H.2: Primary Heart Transplant Surgeon Requirements, H.2.A: Cardiothoracic Surgery Residency Pathway, H.2.B: Twelve-month Heart

**Transplant Fellowship Pathway, H.2.C: Clinical Experience Pathway, H.3: Primary Heart Transplant Physician Requirements, H.3: Primary Heart Transplant Physician Requirements, H.3.A: Twelve-month Transplant Cardiology Fellowship Pathway, H.3.B: Clinical Experience Pathway, H.3.D: Conditional Approval for Primary Transplant Physician, I.2: Primary Lung Transplant Surgeon Requirements, I.2.A: Cardiothoracic Surgery Residency Pathway, I.2.B: Twelve-month Lung Transplant Fellowship Pathway, I.2.C: Clinical Experience Pathway, I.3: Primary Lung Transplant Physician Requirements, I.3.A: Twelve-month Transplant Pulmonary Fellowship Pathway, I.3.B: Clinical Experience Pathway, and I.3.D: Conditional Approval for Primary Transplant Physician**

**Public Comment:** August 2015

**Effective Date:** Upon implementation and notice to OPTN members

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### **Problem Statement**

You'll find the term "foreign equivalent" in the OPTN Bylaws requirements that reference transplant program key personnel. Lacking a more robust definition, this term makes it difficult for members to know if certain staff (or staff being recruited) are qualified to serve as key personnel. This poorly-defined term also makes it difficult for the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to evaluate membership applications because they don't know if a certain board certification or case experience performed outside the United States should be considered a "foreign equivalent."

### **Summary of Changes**

As part of the board-approved Bylaws changes we will:

- Delete the term "foreign equivalent" from the Bylaws in all instances except where it appears in the membership requirements for vascularized composite allograft transplant programs. This includes references to "foreign equivalent" board certifications and designated transplant programs.
- Explicitly allow board certification by the Royal College of Physicians and Surgeons of Canada.
- Create a mechanism for individuals without American or Canadian board certification to qualify as key personnel. With this mechanism, the key personnel applicant must:
  - Be ineligible for American Board Certification
  - Provide a plan for continuing medical education that requires, at a minimum, that the applicant will obtain 60 hours of Category I continuing medical education credits with self-assessment that are relevant to the individual's practice every three years
  - Provide two letters of recommendation from directors of designated transplant programs not employed by the applying hospital

### **What Members Need to Do**

No immediate action is required of members when these changes are implemented. From the day of the implementation and forward, if you submit membership and key personnel change applications, we will evaluate those applications according to the new requirements. Your currently approved program will not

be impacted by these changes until other circumstances make it necessary for you to submit a key personnel application change.

Transplant program key personnel who are not American- or Canadian-board certified and who are approved by the MPSC after these Bylaws changes are implemented must adhere to the continuing medical education plan specified in their application. The OPTN will not regularly monitor your adherence to this plan, but we may request documentation of your adherence, if necessary.

### **Affected Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## ***Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs***

### **E.2 Primary Kidney Transplant Surgeon Requirements**

A designated kidney transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada ~~the foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board American Board of Urology certification in urology~~ is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for ~~42~~16 months to allow time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional ~~42~~16-month period extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Urology, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary kidney transplant surgeon.

- iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
- iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or experience pathways listed below:
- a. The formal 2-year transplant fellowship pathway, as described in Section E.2.A. Formal 2-year Transplant Fellowship Pathway below.
  - b. The kidney transplant program clinical experience pathway, as described in Section E.2.B. Clinical Experience Pathway below.
  - c. The alternative pathway for predominantly pediatric programs, as described in Section E.2.C. Alternative Pathway for Predominantly Pediatric Programs below.

### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a 2-year transplant fellowship if the following conditions are met:

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant over the 2-year period. At least 3 of these procurements must be multiple organ procurements and at least 10 must be from deceased donors. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor



as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows. ~~Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).~~

5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary kidney transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated kidney transplant program, ~~or its foreign equivalent~~. The transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.
2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first assistant. At least 3 of these procurements must be multiple organ procurements and at least 10 must be from deceased donors. These cases must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the transplant program and Chairman of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program.

- b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
- c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

### **E.3 Primary Kidney Transplant Physician Requirements**

A designated kidney transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~the foreign equivalent~~.

In place of current certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary kidney transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-

month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, t~~ The primary transplant physician must have completed at least one of the training or experience pathways listed below:

- a. The 12-month transplant nephrology fellowship pathway, as described in Section E.3.A. Twelve-month Transplant Nephrology Fellowship Pathway below.
- b. The clinical experience pathway, as described in Section E.3.B. Clinical Experience Pathway below.
- c. The 3-year pediatric nephrology fellowship pathway, as described in Section E.3.C. Three-year Pediatric Nephrology Fellowship Pathway below.
- d. The 12-month pediatric transplant nephrology fellowship pathway, as described in Section E.3.D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.
- e. The combined pediatric nephrology training and experience pathway, as described in Section E.3.E. Combined Pediatric Nephrology Training and Experience Pathway below.
- f. The alternative pathway for predominantly pediatric programs, as described in Section E.3.F. Alternative Pathway for Predominantly Pediatric Programs below.
- g. The conditional approval pathway, as described in Section E.3.G. Conditional Approval for Primary Transplant Physician below, if the primary kidney transplant physician changes at an approved kidney transplant program.

### **A. Twelve-month Transplant Nephrology Fellowship Pathway**

Physicians can meet the training requirements for a primary kidney transplant physician during a separate 12-month transplant nephrology fellowship if the following conditions are met:

- ~~1. The physician has current board certification in nephrology by the American Board of Internal Medicine or the foreign equivalent.~~
21. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
32. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.

43. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
54. The physician should have observed at least 3 organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
65. The following letters are submitted directly to the OPTN Contractor:
- A letter from the director of the training program and the supervising qualified kidney transplant physician verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
  - A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The training requirements outlined above are in addition to other clinical requirements for general nephrology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary kidney transplant physician through acquired clinical experience if the following conditions are met:

- The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney ~~Kidney~~ transplant program ~~or the foreign equivalent~~. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.

2. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
3. The physician should have observed at least 3 organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the kidney transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

### **C. Three-year Pediatric Nephrology Fellowship Pathway**

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the following conditions must be met:

1. ~~The physician has current board certification in nephrology by the American Board of Pediatrics, or the foreign equivalent.~~
21. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program's director or the primary physician of the transplant program.

32. The experience caring for pediatric patients occurred with a qualified kidney transplant physician and surgeon at a kidney transplant program that performs an average of at least 10 pediatric kidney transplants a year.
43. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
54. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
65. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

#### **D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway**

The requirements for the primary kidney transplant physician can be met during a separate pediatric transplant nephrology fellowship if the following conditions are met:

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, ~~or the foreign equivalent~~, or is approved by the American Board of Pediatrics to take the certifying exam.
2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant

experience completed at another Kidney transplant program in order to meet these requirements. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.

3. The experience in caring for pediatric patients occurred at a kidney transplant program with a qualified kidney transplant physician and surgeon that performs an average of at least 10 pediatric kidney transplants a year.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
5. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to become the primary transplant physician of a designated kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

## **E. Combined Pediatric Nephrology Training and Experience Pathway**

A physician can meet the requirements for primary kidney transplant physician if the following conditions are met:

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, ~~or the foreign equivalent~~, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME or a Residency Review Committee.
5. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.



## G. Conditional Approval for Primary Transplant Physician

If the primary kidney transplant physician changes at an approved Kidney transplant program, a physician can serve as the primary kidney transplant physician for a maximum of 12 months if the following conditions are met:

- ~~1.~~ ~~The physician has current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
- ~~21.~~ The physician has been involved in the primary care of 23 or more newly transplanted kidney recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
- ~~32.~~ The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- ~~43.~~ The physician has 12 months experience on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program ~~or the foreign equivalent~~. These 12 months of experience must be acquired within a 2-year period.
- ~~54.~~ The physician should have observed at least 3 organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
- ~~65.~~ The program has established and documented a consulting relationship with counterparts at another kidney transplant program.
- ~~76.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
- ~~87.~~ The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other

matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## ***Appendix F: Membership and Personnel Requirements for Liver Transplant Programs***

### **F.2 Primary Liver Transplant Surgeon Requirements**

A designated liver transplant program must have a primary surgeon who meets *all* of the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board American Board of Urology certification in urology~~ certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for ~~12~~16 months to allow time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional 1216-month ~~period~~ extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Urology, the surgeon must:

- a. Be ineligible for American board certification.

- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary liver transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. In addition, the primary transplant surgeon must have completed at least one of the training or experience pathways listed below:

- a. The formal 2-year transplant fellowship pathway, as described in Section F.2.A. Formal 2-year Transplant Fellowship Pathway below.
- b. The liver transplant program clinical experience pathway, as described in Section F.2.B. Clinical Experience Pathway below.
- c. The alternative pathway for predominantly pediatric programs, as described in Section F.2.C. Alternative Pathway for Predominantly Pediatric Programs below.

### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary liver transplant surgeon by completing a 2-year transplant fellowship if the following conditions are met:

1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant during the 2-year period. At least 3 of these procurements must include selection and management of the donor. These procedures must be documented in a log that includes the

- date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
  4. The training was completed at a hospital with a transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as described in *Section F.5. Approved Liver Surgeon Transplant Fellowship Programs* that follows. ~~Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).~~
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
    - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details his or her training and experience in liver transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary liver transplant surgeon through clinical experience gained post-fellowship, if the following conditions are met:

1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated liver transplant program ~~or the foreign equivalent~~. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of liver transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative management of liver recipients.
2. The surgeon has performed at least 30 liver procurements as primary surgeon or first assistant. At least 3 of these procurements must include selection and management of the donor. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The following letters are sent directly to the OPTN Contractor:
  - a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon gained in liver transplantation.

### F.3 Primary Liver Transplant Physician Requirements

A designated liver transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~.

In place of current certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve

an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
- i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary liver transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. In addition, the primary transplant physician must have completed at least one of the training or experience pathways listed below:

- a. The 12-month transplant hepatology fellowship pathway, as described in Section F.3.A. 12-month Transplant Hepatology Fellowship Pathway below.
- b. The clinical experience pathway, as described in Section F.3.B. Clinical Experience Pathway below.
- c. The 3-year pediatric gastroenterology fellowship pathway, as described in Section F.3.C. Three-year Pediatric Gastroenterology Fellowship Pathway below.
- d. The 12-month pediatric transplant hepatology fellowship pathway, as described in Section F.3.D. Pediatric Transplant Hepatology Fellowship Pathway below.
- e. The combined pediatric gastroenterology or transplant hepatology training and experience pathway, as described in Section F.3.E. Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway below.
- f. The alternative pathway for predominantly pediatric programs, as described in Section F.3.F. Alternative Pathway for Predominantly Pediatric Programs below.
- g. The conditional approval pathway, as described in Section F.3.G. Conditional Approval for Primary Transplant Physician below, if the primary liver transplant physician changes at an approved liver transplant program.

Pediatric liver transplant programs should have a board certified pediatrician ~~(or the foreign equivalent)~~ who meets the criteria for primary liver transplant physician. If a qualified pediatric physician is not on staff at the program, a physician meeting the criteria as a primary liver transplant physician for adults can function as the primary liver transplant physician for the pediatric program, if a pediatric gastroenterologist is involved in the care of the pediatric liver transplant recipients.

## B. Clinical Experience Pathway

A physician can meet the requirements for a primary liver transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 50 or more newly transplanted liver recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a designated liver transplant program ~~or the foreign equivalent~~. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
3. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, the location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the liver transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## C. Three-year Pediatric Gastroenterology Fellowship Pathway

A physician can meet the requirements for primary liver transplant physician by completion of 3 years of pediatric gastroenterology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain at least 6 months of clinical care for transplant patients, and meet the following conditions:

1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics, or the ~~foreign equivalent~~ the Royal College of Physicians and Surgeons of Canada.
2. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along with a qualified liver transplant surgeon. The physician was also directly involved in the preoperative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience carried out at another transplant service, to meet these requirements. This care must be documented in a log that includes the date of transplant, the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program's primary transplant physician.
3. The experience caring for pediatric patients occurred at a liver transplant program with a qualified liver transplant physician and a qualified liver transplant surgeon that performs an average of at least 10 liver transplants on pediatric patients per year.
4. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation, the donation process, and the care of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
5. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the pediatric gastroenterology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.



- c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

#### **D. Pediatric Transplant Hepatology Fellowship Pathway**

The requirements for primary liver transplant physician can be met during a separate pediatric transplant hepatology fellowship if the following conditions are met:

1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for at least 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience completed at another liver transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
3. The experience in caring for pediatric liver patients occurred at a liver transplant program with a qualified liver transplant physician and surgeon that performs an average of at least 10 pediatric liver transplants a year.
4. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation, the donation process, and the care of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.

- b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## **E. Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway**

A physician can meet the requirements for primary liver transplant physician if the following conditions are met:

1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and along with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver transplants recipients. This care must be documented in a log that includes at the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
4. The individual has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation of donor, the donation process, and the management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

### **G. Conditional Approval for Primary Transplant Physician**

If the primary liver transplant physician changes at an approved liver transplant program, a physician can serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are met:

- ~~1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
21. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
- ~~32.~~ 32. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- ~~43.~~ 43. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program ~~or the foreign equivalent.~~ These 12 months of experience must be acquired within a 2-year period.
- ~~54.~~ 54. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
- ~~65.~~ 65. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care

of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

- ~~76.~~ The program has established and documented a consulting relationship with counterparts at another liver transplant program.
- ~~87.~~ The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician sends that details the training and experience the physician gained in liver transplantation.

#### **F.4 Requirements for Director of Liver Transplant Anesthesia**

Liver transplant programs must designate a director of liver transplant anesthesia who has expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team.

1. The director of liver transplant anesthesia must be a Diplomate of the American Board of Anesthesiology, ~~or the foreign equivalent.~~
2. In place of current certification by the American Board of Anesthesiology, the director of liver transplant anesthesia must provide to the OPTN Contractor two letters of recommendation from current directors of liver transplant anesthesia at a designated liver program who are not employed by the applying member. These letters must address:
  - a. Why an exception is reasonable.
  - b. The anesthesiologist's overall qualifications to act as a director of liver transplant anesthesiology.
  - c. Any other matters judged appropriate.

#### **F.10 Primary Intestine Transplant Surgeon Requirements**

A designated intestine transplant program must have a primary surgeon who meets *all* of the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing on the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent.~~

In place of current certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary intestine transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. In addition, † The primary transplant surgeon must have completed at least one of the training or experience pathways listed below:
  - a. The primary intestine transplant surgeon full approval pathway, as described in *Section F.10.A* below.
  - b. The primary intestine transplant surgeon conditional pathway, as described in *Section F.10.B* below.

#### **A. Full Intestine Surgeon Approval Pathway**

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include selection and evaluation of the donor. These procurements must include 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in *Section F.13 Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows. ~~Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).~~
5. The following letters are submitted to the OPTN Contractor:
  - a. A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

## **B. Conditional Intestine Surgeon Approval Pathway**

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel and composite grafts and must perform 3 or more intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program, ~~or its foreign equivalent.~~ These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.
2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first assistant. These procurements must include at least 1 procurement of a graft that includes a liver, and selection and evaluation of the donor. This procedure must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.
5. The following letters are sent to the OPTN Contractor:
  - a. A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
  - d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

### **F.11 Primary Intestine Transplant Physician Requirements**

A designated intestine transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or the equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing on the hospital's medical staff.
4. The physician must have current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~.

In place of current certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic

question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
- i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary intestine transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, t~~ The primary physician must have completed at least one of the training or experience pathways listed below:
- a. The primary intestine transplant physician full approval pathway, as described in Section F.11.A below.
  - b. The primary intestine transplant physician conditional pathway, as described in Section F.11.B below.

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care of the transplant recipients.

### **A. Full Intestine Physician Approval Pathway**

Physicians can meet the requirements for a primary intestine transplant physician during the physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through acquired clinical experience (including accumulated training during any fellowships) if all of the following conditions are met:

1. The physician has been directly involved within the last 10 years in the primary care of 7 or more newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of a intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of



- the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
3. The physician must have observed at least 1 isolated intestine transplant and at least 1 combined liver-intestine or multi-visceral transplant.
  4. The following letters are submitted to the OPTN Contractor:
    - a. A letter from the transplant program director documenting the physician's experience and training.
    - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician that details the training and experience the physician gained in intestine transplantation.

## **B. Conditional Intestine Physician Approval Pathway**

Physicians can meet the requirements for approval as primary intestine transplant physician through a conditional approval pathway if *all* of the following conditions are met:

- ~~1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
21. The physician has been involved in the primary care of at least 4 newly transplanted intestine recipients, and has followed these patients for at least 3 months from the time of their transplant. Additionally, the physician must become involved in the care of 3 or more intestine recipients over the next 3 consecutive years. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of a intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
32. The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with intestine failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
43. The physician has 12 months experience as the primary intestine transplant physician or under the direct supervision of a qualified intestine transplant physician along with an intestine transplant surgeon at a designated intestine transplant program, ~~or the foreign equivalent.~~ These 12 months of experience must be acquired within a 2-year period.
54. The physician develops a formal mentor relationship with a primary intestine transplant physician at another approved designated intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.
65. The following letters are submitted to the OPTN Contractor:
  - a. A letter from the qualified intestine transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above

- requirements to become the primary transplant physician of an intestine transplant program.
- b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in intestine transplantation as well as a detailed plan for obtaining full approval.
  - d. A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

## ***Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs***

### **G.2 Primary Pancreas Transplant Surgeon Requirements**

A designated pancreas transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. ~~foreign equivalent~~ In the case of a surgeon who has just completed training and whose ~~board~~ American Board of Urology certification in urology is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for ~~12~~16 months to allow time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional 1216-month period extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Urology, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary pancreas transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

- 5. In addition, t The primary transplant surgeon must have completed at least one of the training or experience pathways listed below:
  - a. The formal 2-year transplant fellowship pathway, as described in Section G.2.A. Formal 2-year Transplant Fellowship Pathway below.
  - b. The pancreas transplant program clinical experience pathway, as described in Section G.2.B. Clinical Experience Pathway below.
  - c. The alternative pathway for predominantly pediatric programs, as described in Section G.2.C. Alternative Pathway for Predominantly Pediatric Programs below.

### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary pancreas transplant surgeon by completing a 2-year transplant fellowship if the following conditions are met:

1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant during the 2-year period. These cases must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.

4. The training was completed at a hospital with a pancreas transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows. ~~Foreign training programs will be reviewed by the MPSC and only those programs that are accepted as equivalent will be granted approval.~~
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
  - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary pancreas transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon or first assistant, at a designated pancreas transplant program ~~or its foreign equivalent~~. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.
2. The surgeon has performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
4. The following letters are submitted directly to the OPTN Contractor:

- a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a pancreas transplant program.
- b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the individual, at its discretion.
- c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

### G.3 Primary Pancreas Transplant Physician Requirements

A designated pancreas transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current board certification in nephrology, endocrinology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~.

In place of current certification in nephrology, endocrinology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary pancreas transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, † The primary transplant physician must have completed at least one of the training or experience pathways listed below:~~

- a. The 12-month pancreas transplant fellowship pathway, as described in *Section G.3.A. Twelve-month Transplant Medicine Fellowship Pathway* below.
- b. The clinical experience pathway, as described in *Section G.3.B. Clinical Experience Pathway* below.
- c. The alternative pathway for predominantly pediatric programs, as described in *Section G.3.C. Alternative Pathway for Predominantly Pediatric Programs* below.
- d. The conditional approval pathway, as described in *Section G.3.D. Conditional Approval for Primary Transplant Physician* below, if the primary pancreas transplant physician changes at an approved pancreas transplant program.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, ~~or the foreign equivalent.~~ The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The physician should have also observed the evaluation of the donor, the donation process, and the management of at least 3 multiple organ donors who donated a

pancreas. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program the physician previously served, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary pancreas transplant physician changes at an approved pancreas transplant program, a physician can serve as the primary pancreas transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, ~~or the foreign equivalent~~. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a pancreas. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.

6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.
7. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the transplant program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## ***Appendix H: Membership and Personnel Requirements for Heart Transplant Programs***

### **H.2 Primary Heart Transplant Surgeon Requirements**

A designated heart transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.



3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Thoracic Surgery or current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada ~~its foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board certification by the American Board of Thoracic Surgery in thoracic surgery~~ board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 24-month period.

In place of current certification by the American Board of Thoracic Surgery, current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Thoracic Surgery, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary heart transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or experience pathways listed below:
  - a. The formal cardiothoracic surgery residency pathway, as described in *Section H.2.A. Cardiothoracic Surgery Residency Pathway* below.
  - b. The 12-month heart transplant fellowship pathway, as described in *Section H.2.B. Twelve-month Heart Transplant Fellowship Pathway* below.
  - c. The heart transplant program clinical experience pathway, as described in *Section H.2.C. Clinical Experience Pathway* below.

- d. The alternative pathway for predominantly pediatric programs, as described in *Section H.2.D. Alternative Pathway for Predominantly Pediatric Programs* below.

### **A. Cardiothoracic Surgery Residency Pathway**

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a cardiothoracic surgery residency if *all* the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the cardiothoracic surgery residency. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon during the cardiothoracic surgery residency. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of Canada, ~~its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.~~
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### **B. Twelve-month Heart Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a 12-month heart transplant fellowship if the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the

- procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon during the 12-month heart transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
  3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
  4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery; or the Royal College of Physicians and Surgeons of Canada; ~~or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.~~
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
    - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### **C. Clinical Experience Pathway**

Surgeons can meet the requirements for primary heart transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program ~~or the foreign equivalent~~. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last

- 2 years. This includes performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the program where the surgeon acquired transplant experience verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
    - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### H.3 Primary Heart Transplant Physician Requirements

A designated heart transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current certification in adult or pediatric cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~.

In place of current board certification in adult or pediatric cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary heart transplant physician.

- iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
- iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, t~~ The primary transplant physician must have completed at least one of the training or experience pathways listed below:
- a. The 12-month transplant cardiology fellowship pathway, as described in Section H.3.A. Twelve-month Transplant Cardiology Fellowship Pathway below.
  - b. The clinical experience pathway, as described in Section H.3.B. Clinical Experience Pathway below.
  - c. The alternative pathway for predominantly pediatric programs, as described in Section H.3.C. Alternative Pathway for Predominantly Pediatric Programs below.
  - d. The conditional approval pathway, as described in Section H.3.D. Conditional Approval for Primary Transplant Physician below, if the primary heart transplant physician changes at an approved heart transplant program.

### **A. Twelve-month Transplant Cardiology Fellowship Pathway**

Physicians can meet the training requirements for primary heart transplant physician during a 12-month transplant cardiology fellowship if the following conditions are met:

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients. This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

4. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology, or an American Board of Pediatrics certified fellowship training program in pediatric cardiology, or a cardiology training program approved by the Royal College of Physicians and Surgeons of Canada, or its foreign equivalent, as accepted by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the Primary Physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program ~~or the foreign equivalent~~. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.

- b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary heart transplant physician changes at an approved heart transplant program, a physician can serve as the primary heart transplant physician for a maximum of 12 months if the following conditions are met:

- ~~1.~~ ~~The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
- ~~21.~~ The physician has 12 months experience on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
- ~~32.~~ The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
- ~~43.~~ The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon at a designated heart transplant program. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
- ~~54.~~ The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
- ~~65.~~ The program has established and documented a consulting relationship with counterparts at another heart transplant program.
- ~~76.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care

of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.

87. The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or an approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

## ***Appendix I: Membership and Personnel Requirements for Lung Transplant Programs***

### **I.2 Primary Lung Transplant Surgeon Requirements**

A designated lung transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.



4. The surgeon must have current certification by the American Board of Thoracic Surgery or current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada ~~its foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board certification by the American Board of Thoracic Surgery in thoracic surgery~~ is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 24-month period.

In place of current certification by the American Board of Thoracic Surgery, current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending board certification by the American Board of Thoracic Surgery, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary lung transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or experience pathways listed below:
- a. The formal cardiothoracic surgery residency pathway, as described in *Section 1.2.A. Cardiothoracic Surgery Residency Pathway* below.
  - b. The 12-month lung transplant fellowship pathway, as described in *Section 1.2.B. Twelve-month Lung Transplant Fellowship Pathway* below.
  - c. The lung transplant program clinical experience pathway, as described in *Section 1.2.C. Clinical Experience Pathway* below.
  - d. The alternative pathway for predominantly pediatric programs, as described in *Section 1.2.D. Alternative Pathway for Predominantly Pediatric Programs* below.

## A. Cardiothoracic Surgery Residency Pathway

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a cardiothoracic surgery residency if the following conditions are met:

1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or heart/lung transplants as primary surgeon or first assistant under the direct supervision of a qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung transplant program. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must also include the other clinical requirements for thoracic surgery.
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada, ~~or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.~~
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

## B. Twelve-month Lung Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a 12-month lung transplant fellowship if the following conditions are met:

1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung

- transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the program.
2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon during the 12-month lung transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
  3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
  4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada, ~~or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.~~
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
    - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

### **C. Clinical Experience Pathway**

Surgeons can meet the requirements for primary lung transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated lung transplant program, ~~or the foreign equivalent~~. At least half of these transplants must be lung procedures, and at least 10 must be performed as the primary surgeon. The surgeon must also have been actively involved with cardiothoracic surgery. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from program where the experience was gained.
2. The surgeon has performed at least 10 lung procurements. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the program where the surgeon gained experience verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

### **I.3 Primary Lung Transplant Physician Requirements**

A designated lung transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The lung transplant physician must have current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~their foreign equivalent~~.

In place of current board certification or achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The hospital must document completion of this continuing education.

- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
- i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary lung transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to Appendix L of these Bylaws.

5. ~~In addition, t~~ The primary transplant physician must have completed at least one of the training or experience pathways listed below:
- a. The 12-month transplant pulmonary fellowship pathway, as described in Section I.3.A. Twelve-month Transplant Pulmonary Fellowship Pathway below.
  - b. The clinical experience pathway, as described in Section I.3.B. Clinical Experience Pathway below.
  - c. The alternative pathway for predominantly pediatric programs, as described in Section I.3.C. Alternative Pathway for Predominantly Pediatric Programs below.
  - d. The conditional approval pathway, as described in Section I.3.D. Conditional Approval for Primary Transplant Physician below, if the primary lung transplant physician changes at an approved lung transplant program.

### **A. Twelve-month Transplant Pulmonary Fellowship Pathway**

Physicians can meet the training requirements for primary lung transplant physician during a 12-month transplant pulmonary fellowship if the following conditions are met:

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.

3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary medicine training program approved by the Royal College of Physicians and Surgeons of Canada. ~~or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.~~
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for primary lung transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 15 or more newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period on an active at a designated lung transplant program ~~or the foreign equivalent.~~ This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the

physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary lung transplant physician changes at an approved lung transplant program, a physician can serve as the primary lung transplant physician for a maximum of 12 months if the following conditions are met:

- ~~1.~~ ~~The physician is a pulmonologist with current board certification in pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
- ~~2~~1. The physician has 12 months of experience on an active lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.
- ~~3~~2. The physician has been involved in the primary care of 8 or more newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be lung transplant recipients. This care must be documented in a recipient log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
- ~~4~~3. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
- ~~5~~4. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
- ~~6~~5. The program has established and documented a consulting relationship with counterparts at another lung transplant program.

76. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary lung transplant physician by the end of the 12 month conditional approval period.
87. The following letters are submitted directly to the OPTN Contractor:
- a. A letter from the supervising lung transplant physician or surgeon of the training program documenting the physician's competence.
  - b. A letter of recommendation from the training program's primary physician and director outlining the physician's overall qualifications to act as primary transplant physician of the transplant program last served by the physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual practicing on site who can meet the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for transplant program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

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# **Revise Facilitated Pancreas Allocation Policy**

<b>Sponsoring Committee:</b>	<b>Pancreas Transplantation</b>
<b>Policy/Bylaws Affected:</b>	<b>Policies 11.6: Administrative Rules and 11.6.A: Facilitated Pancreas Allocation</b>
<b>Public Comment:</b>	<b>August 2015</b>
<b>Effective Date:</b>	<b>Upon implementation and notice to members</b>

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## **Problem Statement**

The current facilitated pancreas allocation system only places a small number of pancreata. Participating programs are not widely accepting and transplanting pancreata resulting from facilitated allocation. This proposal updates the facilitated pancreas allocation mechanics to expedite pancreas organ placement.

## **Summary of Changes**

The two changes will:

1. Change to the eligibility criteria that qualifies transplant programs for the facilitated pancreas allocation list
2. Allow organ procurement organizations (OPOs) to access the list

The change establishes a system in which facilitated pancreas offers are made to those transplant programs that have a recent record of importing deceased donor pancreas organs for transplant. The qualifying criteria will require programs to perform at least five pancreas transplants using imported pancreata within the two previous years. UNOS will calculate the transplant volumes each year to update the list of eligible programs.

OPOs will now have access to use facilitated pancreas allocation, in addition to the Organ Center. An OPO or the Organ Center may now use facilitated pancreas allocation within three hours of donor organ recovery. Both groups will only have access to facilitated pancreas allocation after all local pancreas and kidney-pancreas offers have been declined.

## **What Members Need to Do**

Pancreas transplant programs will collect, maintain, and submit to UNOS all records of imported pancreas transplants on an annual basis, as they normally do. These data are used to determine whether programs are eligible for the facilitated pancreas allocation list.

OPOs need to know they must make facilitated pancreas offers in order of the match run. Additionally, staff making these offers should know that this change allows for offers to be made within three hours, as opposed to one hour, of a scheduled organ donor recovery and after all local pancreas and kidney-pancreas offers have been declined.

## **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## **11.6 Administrative Rules Facilitated Pancreas Allocation**

### **11.6.A Facilitated Pancreas Allocation Transplant Program Qualifications**

The A transplant hospital program must have a written agreement to participate in facilitated pancreas allocation. qualifies to receive facilitated pancreas offers if within the two previous years it has transplanted a minimum of five pancreas recovered from deceased donors outside its DSA. This includes pancreas transplanted as part of a multi-organ transplant.

The OPO can use Facilitated Pancreas Allocation to allocate a pancreas if either occurs:

- No candidate accepts a pancreas offer from the Organ Center within five hours of the first offer
- The Organ Center is notified that procurement of the pancreas will occur within one hour

The Organ Center must then offer the pancreas to pancreas candidates in the order of the match run who meet the following criteria:

1. Have not previously received an offer for that pancreas.
2. Are registered at a transplant hospital that previously agreed to accept any pancreas offered using the Facilitated Pancreas Allocation and that may have been procured outside of the transplant hospital's DSA.

Transplant programs that qualify for facilitated pancreas allocation must notify the OPTN Contractor in writing if they do not wish to participate.

### **11.6.B Facilitated Pancreas Offers**

OPOs and the Organ Center are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or Organ Center must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have access to facilitated allocation after all local pancreas and kidney-pancreas offers have been declined.

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# ***Establishing Pediatric Training and Experience Requirements in the Bylaws***

**Sponsoring Committee:** Pediatric Transplantation

**Policy/Bylaws Affected:** OPTN Bylaws appendices E.2: Primary Kidney Transplant Surgeon Requirements, E.3: Primary Kidney Transplant Physician Requirements, E.5: Kidney Transplant Programs that Register Candidates Less than 18 Years Old, F.3: Primary Liver Transplant Surgeon Requirements, F.4: Primary Liver Transplant Physician Requirements, Appendix F.7: Liver Transplant Programs that Register Candidates Less than 18 Years Old, G.8: Pancreas Transplant Programs that Register Candidates Less than 18 Years Old, H.2: Primary Heart Transplant Surgeon Requirements, H.3: Primary Heart Transplant Physician Requirements, H.4: Heart Transplant Programs that Register Candidates Less than 18 Years Old, I.4: Lung Transplant Programs that Register Candidates Less than 18 Years Old, L.17: Interviews, and L.18: Hearings

**Public Comment:** January 2015 and August 2015

**Effective Date:** Upon implementation and notice to OPTN members

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## **Problem Statement**

The National Organ Transplant Act (NOTA) requires that the OPTN “recognize the differences in health and in organ transplantation issues between children [less than 18 years old] and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.”<sup>1</sup> Although pediatric transplantation is an accepted subspecialty within the field of transplantation, the current OPTN Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants. As early as 1993, the Membership and Professional Standards Committee (MPSC) has sought guidance from the Pediatric Transplantation Committee in establishing pediatric requirements so it could better assess key personnel applications.

## **Summary of Changes**

The Bylaws will require that a designated transplant program have an approved pediatric component in order to perform kidney, liver, and heart transplants in patients less than 18 years old. To be approved for a pediatric component, a program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician who will serve as key personnel.

## **What Members Need to Do**

UNOS will distribute a pediatric component application to any member transplant program that has had at least one pediatric patient on its waiting list in the last five years. If you do not automatically receive an application based on this criteria, contact the UNOS Membership Analyst for your region to request one. If

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<sup>1</sup> 42 USC Sec. 274 (b)(2)(M).

you receive an application but don't intend to apply, please document your intention and submit it to UNOS.

Your program must complete and submit your application to UNOS within 90 days in order to guarantee that we process them before the Bylaws are implemented. UNOS and the MPSC will process each application over the next 18 months. We will notify you of the status of your application before the Bylaws are implemented.

Once the Bylaws are implemented, if your program has pediatric patients on the waiting list and you don't have approval for a pediatric component, you must follow the transition plan described in Appendix K.5: *Transition Plan during Long-term Inactivity, Termination, or Withdrawal*.

If your liver or heart transplant program does not have a pediatric component, you may register a patient less than 18 years old on the waiting list if you believe the transplant would prevent a serious or imminent threat to your patient's health or safety and if the patient qualifies as pediatric liver or heart Status 1A. Your program must submit a pediatric membership exception request to UNOS within 72 hours of the candidate's registration. The MPSC will retrospectively consult with the Pediatric Transplantation Committee to determine whether an emergency was present and that it was medically inadvisable or commercially impractical to transport the patient to a program with a pediatric component. If the MPSC denies an emergency exception request, that candidate's registration will be in violation of OPTN obligations and result in punitive action. Approval of an exception is limited to the individual case and does not mean that your program has been approved for a pediatric component.

### **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

## ***Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs***

### **E.2 Primary Kidney Transplant Surgeon Requirements**

#### **~~C. Alternative Pathway for Predominantly Pediatric Programs~~**

~~If a surgeon does not meet the requirements for primary kidney transplant surgeon through either the transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in Sections E.2.A or E.2.B above.~~
- ~~2. The surgeon has maintained a current working knowledge of all aspects of kidney transplantation and patient care, defined as direct involvement in kidney transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon,~~

~~director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~

~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board of Directors.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

### **E.3 Primary Kidney Transplant Physician Requirements**

#### **F. ~~Alternative Pathway for Predominantly Pediatric Programs~~**

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1. That the physician's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections E.3.A through E.3.E* above.~~
- ~~2. The physician has maintained a current working knowledge of all aspects of kidney transplantation, defined as direct involvement in kidney transplant patient care within the last 2 years.~~
- ~~3. The physician receives a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

## **G.F. Conditional Approval for Primary Transplant Physician**

### **E.5 Kidney Transplant Programs that Register Candidates Less than 18 Years Old**

A designated kidney transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated kidney transplant program must identify a qualified primary pediatric kidney transplant surgeon and a qualified primary pediatric kidney transplant physician, as described below.

#### **A. Primary Pediatric Kidney Transplant Surgeon Requirements**

A pediatric component at a designated kidney transplant program must have a primary pediatric surgeon who meets *all* of the following requirements:

1. The surgeon meets *all* of the requirements described in *Section E.2: Primary Kidney Transplant Surgeon Requirements*, including completion of at least *one* of the following training or experience pathways:
  - The formal 2-year transplant fellowship pathway as described in *Section E.2.A: Formal 2-year Transplant Fellowship Pathway*
  - The kidney transplant program clinical experience pathway, as described in *Section E.2.B: Clinical Experience Pathway*
2. The surgeon has performed at least 10 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 3 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care within the last 2 years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, HLA typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

#### **B. Primary Pediatric Kidney Transplant Physician Requirements**

A pediatric component at a designated kidney transplant program must have a primary pediatric physician who meets *all* of the requirements described in *Section E.3: Primary Kidney Transplant Physician Requirements*. In addition, the primary pediatric transplant physician must have

completed at least one of the training or experience pathways listed below:

- The 3-year pediatric nephrology fellowship pathway, as described in *Section E.3.C: Three-year Pediatric Nephrology Fellowship Pathway*
- The 12-month pediatric transplant nephrology fellowship pathway, as described in *Section E.3.D: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway*
- The combined pediatric nephrology training and experience pathway, as described in *Section E.3.E: Combined Pediatric Nephrology Training and Experience Pathway*

### **C. Conditional Approval for a Pediatric Component**

A designated kidney transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric kidney physician who meets all of the requirements described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements* and a surgeon who meets all of the following requirements:
  - a. The surgeon meets all of the requirements described in *Section E.2: Primary Kidney Transplant Surgeon Requirements*, including completion of at least one of the following training or experience pathways:
    - The formal 2-year transplant fellowship pathway as described in *Section E.2.A: Formal 2-year Transplant Fellowship Pathway*
    - The kidney transplant program clinical experience pathway, as described in *Section E.2.B: Clinical Experience Pathway*
  - b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care in the last 2 years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the pediatric transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
2. The program has a qualified primary pediatric kidney surgeon who meets all of the requirements described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements* and a physician who meets all of the following requirements:
  - a. The physician has current board certification in pediatric nephrology by the American

Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.

- b. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
- c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted kidney recipients and followed 15 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
- d. The physician has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipients including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) – Ped of the ACGME or a Residency Review Committee.
- e. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
- f. The following letters are submitted directly to the OPTN Contractor:
  - i. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - ii. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary pediatric surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - iii. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.



A designated kidney transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

#### **D. Full Approval for a Pediatric Component following Conditional Approval**

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC can consider granting a 24-month conditional approval extension to the designated kidney transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated kidney transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated kidney transplant program is unable to demonstrate that it has both a pediatric primary kidney surgeon onsite that meets *all* of the requirements as described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements* and a pediatric primary kidney physician onsite that meets *all* of the requirements as described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

### **E.56 Kidney Transplant Programs that Perform Living Donor Recovery**

## ***Appendix F: Membership and Personnel Requirements for Liver Transplant Programs***

### **F.3 Primary Liver Transplant Surgeon Requirements**

#### **~~C. Alternative Pathway for Predominantly Pediatric Programs~~**

~~If a surgeon does not meet the requirements for primary liver transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.2.A or F.2.B* above.~~
- ~~2. The surgeon has maintained a current working knowledge of all aspects of liver transplantation and patient care, defined as direct involvement in liver transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon.~~

~~as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~

~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

## **F.4 Primary Liver Transplant Physician Requirements**

### **F. Alternative Pathway for Predominantly Pediatric Programs**

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1. That the physician's liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.3.A through F.3.E* above.~~
- ~~2. The physician has maintained a current working knowledge of all aspects of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.~~
- ~~3. The physician submits a letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~

- ~~Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

## **G.F. Conditional Approval for Primary Transplant Physician**

### **F.7 Liver Transplant Programs that Register Candidates Less than 18 Years Old**

A designated liver transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated liver transplant program must identify a qualified primary pediatric liver transplant surgeon and a qualified primary pediatric liver transplant physician, as described below.

#### **A. Primary Pediatric Liver Transplant Surgeon Requirements**

A pediatric component at a designated liver transplant program must have a primary pediatric surgeon who meets *all* of the following requirements:

1. The surgeon meets *all* of the requirements described in *Section F.2: Primary Liver Transplant Surgeon Requirements*, including completion of at least *one* of the following training or experience pathways:
  - The formal 2-year transplant fellowship pathway as described in *Section F.2.A: Formal 2-year Transplant Fellowship Pathway*
  - The liver transplant program clinical experience pathway, as described in *Section F.2.B: Clinical Experience Pathway*
2. The surgeon has performed at least 15 liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 8 of these liver transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the pediatric transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

## **B. Primary Pediatric Liver Transplant Physician Requirements**

A pediatric component at a designated liver transplant program must have a primary pediatric physician who meets all of the requirements described in Section F.3: Primary Liver Transplant Physician Requirements. In addition, the primary pediatric transplant physician must have completed at least one of the training or experience pathways listed below:

- The 3-year pediatric gastroenterology fellowship pathway, as described in Section F.3.C: Three-year Pediatric Gastroenterology Fellowship Pathway
- The 12-month pediatric transplant hepatology fellowship pathway, as described in Section F.3.D: Pediatric Transplant Hepatology Fellowship Pathway
- The combined pediatric gastroenterology or transplant hepatology training and experience pathway, as described in Section F.3.E: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway

## **C. Conditional Approval for a Pediatric Component**

A designated liver transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric liver physician who meets all of the requirements described in Section F.6.B: Primary Pediatric Liver Transplant Physician Requirements and a surgeon who meets all of the following requirements:
  - a. The surgeon meets all of the requirements described in Section F.2: Primary Liver Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
    - The formal 2-year transplant fellowship pathway as described in Section F.2.A: Formal 2-year Transplant Fellowship Pathway
    - The liver transplant program clinical experience pathway, as described in Section F.2.B: Clinical Experience Pathway
  - b. The surgeon has performed at least 7 liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 2 of these liver transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
2. The program has a qualified primary pediatric liver surgeon who meets all of the requirements described in Section F.6.A: Primary Pediatric Liver Transplant Surgeon

Requirements and a physician who meets all of the following requirements:

- a. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
- b. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
- c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted pediatric liver recipients and followed 10 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver transplants recipients. This care must be documented in a log that includes at the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
- d. The individual has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- e. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation of donor, the donation process, and the management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
- f. The following letters are submitted directly to the OPTN Contractor:
  - i. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
  - ii. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - iii. A letter from the physician that details the training and experience the physician gained in liver transplantation.

A designated liver transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

#### **D. Full Approval for a Pediatric Component following Conditional Approval**

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated liver transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated liver transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated liver transplant program is unable to demonstrate that it has both a pediatric primary liver surgeon onsite that meets *all* of the requirements as described in *Section F.6.A: Pediatric Primary Liver Transplant Surgeon Requirements* and a pediatric primary liver physician onsite that meets *all* of the requirements as described in *Section F.6.B: Pediatric Primary Liver Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

#### **E. Emergency Pediatric Membership Exceptions**

A designated liver transplant program that does not have a pediatric component may register a patient less than 18 years old on the waiting list if *all* the following conditions are met:

1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety
2. The patient is pediatric Status 1A according to *Policy 9: Allocation of Livers and Liver-Intestines*.

The transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.

The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate *all* the following:

1. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety
2. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated liver transplant program with an approved pediatric component
3. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant

If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.

Approval of an emergency pediatric membership exception request does not grant the transplant program approval of the pediatric component.

## **F.78 Liver Transplant Programs that Perform Living Donor Recovery**

*[Subsequent headings affected by the renumbering of this policy will also be changed as necessary.]*

# **Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs**

## **G.8 Pancreas Transplant Programs that Register Candidates Less than 18 Years Old**

A designated pancreas transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated pancreas transplant program must identify a qualified primary pediatric pancreas transplant surgeon and a qualified primary pediatric pancreas transplant physician, as described below.

### **A. Primary Pediatric Pancreas Transplant Surgeon Requirements**

A pediatric component at a designated pancreas transplant program must have a primary pediatric surgeon who meets *all* of the requirements described in *Section G.2: Primary Pancreas Transplant Surgeon Requirements*.

### **B. Primary Pediatric Pancreas Transplant Physician Requirements**

A pediatric component at a designated pancreas transplant program must have a primary pediatric physician who meets *all* of the requirements described in *Section G.3: Primary Pancreas Transplant Physician Requirements*.

# **Appendix H: Membership and Personnel Requirements for Heart Transplant Programs**

## **H.2 Primary Heart Transplant Surgeon Requirements**

### **~~D. Alternative Pathway for Predominantly Pediatric Programs~~**

~~If a surgeon does not meet the requirements for primary heart transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's heart transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections H.2.A through H.2.C* above.~~

- ~~2. The surgeon has maintained a current working knowledge of all aspects of heart transplantation and patient care, defined as direct involvement in heart transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~▪ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~▪ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

### **H.3 Primary Heart Transplant Physician Requirements**

#### **~~C. Alternative Pathway for Predominantly Pediatric Programs~~**

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1. That the physician's heart transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections H.3.A and H.3.B* above.~~
- ~~2. The physician has maintained a current working knowledge of all aspects of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.~~
- ~~3. The physician submits a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN Obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~



~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~▪ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~▪ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

## **D.C. Conditional Approval for Primary Transplant Physician**

### **H.4 Heart Transplant Programs that Register Candidates Less than 18 Years Old**

A designated heart transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated heart transplant program must identify a qualified primary pediatric heart transplant surgeon and a qualified primary pediatric heart transplant physician, as described below.

#### **A. Primary Pediatric Heart Transplant Surgeon Requirements**

A pediatric component at a designated heart transplant program must have a primary pediatric surgeon who meets *all* of the following requirements:

1. The surgeon meets *all* of the requirements described in *Section H.2: Primary Heart Transplant Surgeon Requirements*.
2. The surgeon has performed at least 8 heart transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 4 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The surgeon has maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years. This includes performing the pediatric transplant operation, donor selection, use of mechanical assist devices, pediatric recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow up.

#### **B. Primary Pediatric Heart Transplant Physician Requirements**

A pediatric component at a designated heart transplant program must have a primary pediatric physician who meets *all* of the following requirements:

1. The physician meets *all* of the requirements described in *Section H.3: Primary Heart Transplant Physician Requirements* and has current certification in pediatric cardiology by the

American Board of Pediatrics.

2. The physician has been directly involved in the primary care of at least 8 heart transplant recipients less than 18 years old at the time of transplant. At least 4 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. This care must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The physician has maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow up.

### **C. Conditional Approval for a Pediatric Component**

A designated heart transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric heart physician who meets all of the requirements described in *Section H.4.B: Primary Pediatric Heart Transplant Physician Requirements* and a surgeon who meets all of the following requirements:
  - a. The surgeon meets all of the requirements described in *Section H.2: Primary Heart Transplant Surgeon Requirements*, including completion of at least one of the following training or experience pathways:
    - The formal cardiothoracic surgery residency pathway, as described in Section H.2.A: Cardiothoracic Surgery Residency Pathway
    - The 12-month heart transplant fellowship pathway, as described in Section H.2.B: Twelve-month Heart Transplant Fellowship Pathway
    - The heart transplant program clinical experience pathway, as described in Section H.2.C: Clinical Experience Pathway
  - b. The surgeon has performed at least 4 heart transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, pediatric recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow up.

2. The program has a qualified primary pediatric heart surgeon who meets all of the requirements described in *Section H.4.A: Primary Pediatric Heart Transplant Surgeon Requirements* and a physician who meets all of the following requirements:
  - a. The physician meets all of the requirements described in *Section H.3: Primary Heart Transplant Physician Requirements* and has current certification in pediatric cardiology by the American Board of Pediatrics.
  - b. The physician has been directly involved in the primary care of at least 4 heart transplant recipients less than 18 years old at the time of transplant. At least 1 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. This care must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The physician has maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow up.

A designated heart transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

#### **D. Full Approval for a Pediatric Component following Conditional Approval**

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated heart transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete all of the requirements within the initial 24-month period.

Once the designated heart transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated heart transplant program is unable to demonstrate that it has both a primary pediatric heart surgeon onsite that meets all of the requirements as described in *Section H.4.A: Primary Pediatric Heart Transplant Surgeon Requirements* and a primary pediatric heart physician onsite that meets all of the requirements as described in *Section H.4.B: Primary Pediatric Heart Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

## **E. Emergency Pediatric Membership Exceptions**

A designated heart transplant program that does not have a pediatric component may register a patient less than 18 years old on the waiting list if all the following conditions are met:

1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety
2. The patient is pediatric Status 1A according to *Policy 6: Allocation of Heart and Heart-Lungs*

The transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.

The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate all the following:

1. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety
2. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated heart transplant program with an approved pediatric component
3. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant

If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.

Approval of an emergency pediatric membership exception request does not grant the transplant program approval of the pediatric component.

# ***Appendix I: Membership and Personnel Requirements for Lung Transplant Programs***

## **I.4 Lung Transplant Programs that Register Candidates Less than 18 Years Old**

A designated lung transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated lung transplant program must identify a qualified primary pediatric lung transplant surgeon and a qualified primary pediatric lung transplant physician, as described below.

### **A. Primary Pediatric Lung Transplant Surgeon Requirements**

A pediatric component at a designated lung transplant program must have a primary pediatric surgeon who meets all of the requirements described in *Section I.2: Primary Lung Transplant Surgeon Requirements*.

### **B. Primary Pediatric Lung Transplant Physician Requirements**

A pediatric component at a designated lung transplant program must have a primary pediatric

physician who meets all of the requirements described in Section I.3: Primary Lung Transplant Physician Requirements.

## **Appendix L: Reviews, Actions, and Due Process**

### **L.17. Interviews**

An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural rules followed for hearings. The member will be informed of the reasons for the interview and may present any information it considers useful and relevant.

#### **A. Members' Right to an Interview**

The member will have the right to an interview when:

1. A Letter of Reprimand is recommended.
2. An adverse action is recommended.
3. A membership application or application for designated transplant program status is rejected.
4. A pediatric membership exception request is rejected.

However, a member has no right to an interview when a potential violation is being reviewed through the Imminent Threat Review pathway. After the interview is completed, the MPSC will promptly provide a summary of the interview to the member.

### **L.18. Hearings**

If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse action without recommendation from the MPSC, the member is entitled to a hearing.

#### **A. Members' Right to a Hearing**

The member has a right to a hearing when an adverse action is:

1. Recommended by the MPSC.
2. Recommended by a subcommittee of the MPSC, if the action is the rejection of an initial membership application or application for designated transplant program status.
3. A result of a determination regarding a potential violation undergoing an Imminent Threat Review.
4. Taken by the Board of Directors or the Executive Committee notwithstanding a favorable recommendation by the MPSC or standing subcommittee of the MPSC under circumstances where no right to a hearing existed.
5. Taken by the Board of Directors or the Executive Committee on its own without a prior recommendation by the MPSC.

The member also has a right to a hearing when the MPSC or a subcommittee of the MPSC rejects a pediatric membership exception request.

If the Board of Directors determines, based on available evidence that a potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the Board may take action even if the member has not had the opportunity for a hearing.

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# ***Proposal to Modify Pediatric Lung Allocation Policy***

**Sponsoring Committee:** Thoracic Organ Transplantation

**Policy/Bylaws Affected:** 10.4.B: Allocation of Lungs by Blood Type, 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old, 10.4.D: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old, and 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old, 3.4.H: In Utero Candidate Registrations, 5.3.C: Pediatric Heart Acceptance Criteria, 6.1: Status Assignments, 6.1.D: Pediatric Heart Status 1A Requirements, 6.1.E: Pediatric Heart Status 1B Requirements, 6.1.F: Pediatric Heart Status 2 Requirements, 6.3: Status Exceptions, 6.3.A: RRB and Committee Review of Status Exceptions, 6.4: Waiting Time, 6.5.A: Allocation of Hearts by Blood Type, 6.5.B: Sorting Within Each Classification, 6.5.C: Allocation of Hearts from Donors at Least 18 Years Old, 6.5.D: Allocation of Hearts from Donors Less Than 18 Years Old, 6.5.E: Allocation of Hearts from Donors Less Than 18 Years Old

**Public Comment:** August 2015

**Effective Date:** Pending implementation and notice to OPTN members

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## **Problem Statement**

Current policy only permits child donor lungs (0-11 years old) to be more broadly shared geographically through Zone B. This means that lungs from child deceased donors are not being offered to adolescent candidates (12-17 years old) beyond Zone A before those lungs are offered to adult candidates. Lungs from adolescent deceased donors are not offered to either adolescent or child candidates of the same age and medical urgency status across a wider area before being offered to adult candidates more proximate to the donor.

Infant lung candidates are especially disadvantaged by a lack of access to organs that are the appropriate size. While current policy allows candidates that were registered before they turned two-years old to receive hearts from deceased donors of any blood type, intended blood type incompatible transplants are not permitted for the 12-14 lung candidates that were registered before their 2<sup>nd</sup> birthday each year. Candidates less than one year old have the highest percentage of removal from the waiting list because they died or were too sick to transplant. OPTN data also show that the percentage of donors for whom there are no candidates on the match run is substantially higher for donors 0-2 years old than any other age group. While at times this is because the candidates currently waiting are not the appropriate size, it may also be due to the unavailability of an appropriate candidate with the right blood type.

## **Summary of Changes**

This proposal provides more opportunities for candidates younger than 18 years of age to receive offers from donors who are also younger than 18. Simulation modeling suggests that the newly approved policy

will increase transplant rates for children, especially those between the ages of 6 and 11, without significantly affecting adult candidates.

The revised policy also will allow lung candidates listed before they are two years old to be considered for intended blood type incompatible matching, if their transplant program chooses to do so. This should allow greater access to transplantation because it is less common to locate lung donors younger than age two who are an identical blood type match.

### **What Members Need to Do**

Programs should consider the appropriateness of registering patients that meet the following criteria as eligible to accept an intended blood type incompatible lung:

- Priority 1, less than 1 year old
- Priority 1, at least 1 year old but registered before turning 2 years old, with isohemagglutinin titers less than or equal to 1:16.

If you register your candidate as willing to receive an intended blood type incompatible offer, your program will need to submit additional data. If your candidate is less than 2 years old at time you register them on the waiting list, you must report whether they are willing to accept an offer of any blood type for that candidate. If yes, then you must submit isohemagglutinin titers in Waitlist<sup>SM</sup> when you initially report that a candidate is willing to accept an intended blood type incompatible lung and then update these titers every 30 days. For a recipient of a intended blood type incompatible lung, you must submit isohemagglutinin titers from a blood sample taken within 24 hours before transplant and from a recent sample if graft loss or death occurs within one year post-transplant.

Organ Procurement Organizations (OPOs) will need to educate their staff on the new allocation algorithm.

### **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

#### **10.1.F The LAS Calculation**

The LAS calculation uses *all* of the following measures:

- Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waiting List Urgency Measure.
- Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

$$\text{LAS} = \frac{100 * [\text{PTAUC} - 2 * \text{WLAUC} + 730]}{1095}$$

**Table 10-2: LAS Calculation Values**

Where...	Includes...
$\text{PTAUC} = \sum_{k=0}^{364} S_{\text{TX}}(k)$	<p>PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.</p> <p><math>\beta_i</math> = the coefficient for characteristic i from the waiting list measure, according to <i>Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients</i>.</p>
$S_{\text{TX}}(t) = S_{\text{TX},0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \dots + \alpha_q Y_q}}$	<p><math>S_{\text{TX}}(t)</math> = the expected post-transplant survival probability at time t for an individual candidate.</p> <p><math>Y_i</math> = the value of the <math>i^{\text{th}}</math> characteristic for an individual candidate</p> <p><math>\alpha_j</math> = the coefficient for characteristic j from the post-transplant survival measure, according to <i>Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients</i>.</p>
$\text{WLAUC} = \sum_{k=0}^{364} S_{\text{WL}}(k)$	<p>WLAUC = the area under the waiting list survival probability curve during the next year.</p>
$S_{\text{WL}}(t) = S_{\text{WL},0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \dots + \beta_p X_p}}$	<p><math>S_{\text{WL},0}(t)</math> = the baseline waiting list survival probability at time t, according to <i>Table 10-811: Baseline Waiting List Survival (SWL(t)) Probability</i>.</p> <p><math>S_{\text{TX},0}(t)</math> = the baseline post-transplant survival probability at time t, according to <i>Table 10-912: Baseline Post-Transplant Survival (S<sub>TX</sub>(t)) Probability</i>.</p> <p><math>S_{\text{WL}}(t)</math> = the expected waiting list survival probability at time t for an individual candidate</p> <p><math>X_i</math> = the value of the <math>i^{\text{th}}</math> characteristic for an individual candidate.</p>

Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See Policy 10.1.F.i: Lung Disease Diagnosis Groups for specific information on each diagnosis group.



**Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients**

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (year)	$0.0083990318885565 * \text{age}$
2. Bilirubin (mg/dL)	$0.0431682188302477 * (\text{bilirubin} - 1)$ if bilirubin is more than 1.0 mg/dL  0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Diagnosis Group B  0 for Diagnosis Groups A, C, and D
4. Body mass index (BMI) (kg/m <sup>2</sup> )	$0.1261444133358100 * (20 - \text{BMI})$ for BMI less than 20 kg/m <sup>2</sup>  0 if BMI is at least 20 kg/m <sup>2</sup>
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 L/min/m <sup>2</sup>  0 if the cardiac index is at least 2 L/min/m <sup>2</sup>
6. Central venous pressure (CVP) (mm Hg) at rest, prior to any exercise	$0.0173841981251578 * (\text{CVP} - 7)$ for CVP greater than 7 mm Hg (Diagnosis Group B only)  0 if less than or equal to 7 mm Hg for Diagnosis Group B  0 for candidates in Diagnosis Groups A, C, and D
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed  0 if no continuous mechanical ventilation needed
8. Creatinine (serum) (mg/dL)	$0.5034346761960600 * \text{creatinine}$ if candidate is at least 18 years old  0 if candidate is less than 18 years old
9. Diabetes	0.4680254026735700 if diabetic  0 if not diabetic
10. Diagnosis Group A	0
11. Diagnosis Group B	1.5774243292137200
12. Diagnosis Group C	1.2313926484343600
13. Diagnosis Group D	0.6259577164157700
14. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.6680518055684700
15. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	-0.6278657824830000
16. Detailed diagnosis: Lymphangiomyomatosis (Diagnosis Group A only)	-0.3162937838984600

For this covariate:	The following coefficient is used in the LAS calculation:
17. Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Diagnosis Group D only)	0.4453284411081100
18. Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.2091170018125500
19. Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.4577749354638600
20. Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.9330846239906700
21. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Diagnosis Group D  0 if FVC is greater than or equal to 80% for Diagnosis Group D  0 for candidates in Diagnosis Groups A, B, and C
22. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living  0 if some or total assistance needed with activities of daily living
23. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0213187586203456*O <sub>2</sub> for Diagnosis Group B  0.1188479817592500*O <sub>2</sub> for Diagnosis Groups A, C, and D
24. PCO <sub>2</sub> (mm Hg): current	0.1104609835819100*PCO <sub>2</sub> /10 if PCO <sub>2</sub> is at least 40 mm Hg
25. PCO <sub>2</sub> increase of at least 15%	0.2331149280428300 if PCO <sub>2</sub> increase is at least 15%  0 if PCO <sub>2</sub> increase is less than 15%
26. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg  0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less  0.0462410402627318*PA systolic/10 for Diagnosis Groups B, C, and D

For this covariate:	The following coefficient is used in the LAS calculation:
27. Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	$-0.0844896372724000 \times \text{Six-minute-walk distance} / 100$

Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

**Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients**

For this variable:	The following is used in the LAS calculation:
1. Age (years)	0.0246579831271869*(age-45) if candidate is greater than 45 years old  0 if candidate is 45 years old or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if candidate is at least 18 years old  0 if candidate is less than 18 years old
3. Creatinine increase of at least 150%	0.7708616024698100 if increase in creatinine is at least 150%, and the higher value determining this increase is at least 1 mg/dL  0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL  0 if increase in creatinine less than 150%
4. Cardiac index (L/min/m <sup>2</sup> ) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m <sup>2</sup>  0 if at least 2 L/min/m <sup>2</sup>
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed  0 if no continuous mechanical ventilation needed
6. Diagnosis Group A	0
7. Diagnosis Group B	0.6115547319209300
8. Diagnosis Group C	0.3627014422464200
9. Diagnosis Group D	0.4641392063023200

For this variable:	The following is used in the LAS calculation:
10. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.1889100379099400
11. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	0.9146727886744700
12. Detailed diagnosis: Lymphangiomyomatosis (Diagnosis Group A only)	-1.5194416206749400
13. Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only)	-1.2050508750702600
14. Detailed diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.0723596761367600
15. Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.0437880049066331
16. Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	-0.1389363636019300
17. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0747978926517300*O <sub>2</sub> for Diagnosis Group A  0.0164276945879309*O <sub>2</sub> for Diagnosis Groups B, C, and D
18. Functional Status	-0.1900086366785100 if no assistance needed with activities of daily living  0 if some or total assistance needed with activities of daily living
19. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-Six-minute-walk distance)  0 if six-minute-distance-walked is at least 1,200 feet

See *Policy 10.5: Probability Data Used in the LAS Calculation* for *Tables 10-118* and *10-129* that provide data used in the LAS calculation.

#### **10.4.B Allocation of Lungs by Blood Type**

A candidate whose blood type is identical to the donor's will receive the single or double lung offer before a candidate whose blood type is compatible but not identical with the donor's. A deceased donor's blood type compatibility with a lung candidate is defined in *Table 10-5* below.

**Table 10-5: Deceased Donor Blood Type Compatibility with a Lung Candidate**

Deceased Donor's Blood Type	Candidate's Blood Type			
	O	A	B	AB
O	Identical	Compatible	Compatible	Compatible
A	Screened*	Identical	Screened*	Compatible
B	Screened*	Screened*	Identical	Compatible
AB	Screened*	Screened*	Screened*	Identical

\*Screened from match run, unless eligible for intended blood group incompatible offers according to Policy 10.4.B.i

**10.4.B.i Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs**

Candidates will be eligible for intended blood group incompatible deceased donor lungs if they meet the requirements according to Table 10-6 below.

**Table 10-6: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs**

If the candidate is:	And meets <i>all</i> of the following:
<u>Less than one year old at the time of the match run</u>	<ol style="list-style-type: none"> <li>1. Is priority 1.</li> <li>2. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.</li> </ol>
<u>At least one year old at the time of the match run</u>	<ol style="list-style-type: none"> <li>1. Is registered prior to turning two years old.</li> <li>2. Is priority 1.</li> <li>3. Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.</li> </ol>

**10.4.B.ii Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung**

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN Contractor.

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood group incompatible lung, according to Table 10-7 below, at *all* of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood group incompatible lung.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood group incompatible lung.

**Table 10-7: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung**

<u>If the candidate's blood type is:</u>	<u>Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:</u>
A	Anti-B
B	Anti-A
O	Anti-A and Anti-B

Accurate isohemagglutinin titers must be reported for recipients of an intended blood group incompatible lung, according to *Table 10-8*, as follows:

1. At transplant, from a blood sample taken within 24 hours prior to transplant.
2. If graft loss occurs within one year after transplant from the most recent sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

**Table 10-8: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Group Incompatible Lung**

<u>If the deceased donor's blood type is:</u>	<u>And the recipient's blood type is:</u>	<u>Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:</u>
<u>A</u>	<u>B or O</u>	<u>Anti-A</u>
<u>B</u>	<u>A or O</u>	<u>Anti-B</u>
<u>AB</u>	<u>A</u>	<u>Anti-B</u>
<u>AB</u>	<u>B</u>	<u>Anti-A</u>
<u>AB</u>	<u>O</u>	<u>Anti-A and Anti-B</u>

**10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old**

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-59* below.

**Table 10-59: Allocation of Lungs from Deceased Donors at Least 18 Years Old**

<b>Classification</b>	<b>Candidates that are included within the:</b>	<b>And are:</b>
<b>1</b>	OPO's DSA	At least 12 years old, blood type identical to the donor
<b>2</b>	OPO's DSA	At least 12 years old, blood type compatible with the donor
<b>3</b>	OPO's DSA	Priority 1, blood type identical to the donor Priority 1 and <i>one</i> of the following: <u>Less than 12 years old and blood type identical to the donor</u> <u>Less than 1 year old and blood type compatible with the donor</u> <u>Less than 1 year old and eligible for intended blood group incompatible offers</u>

Classification	Candidates that are included within the:	And are:
4	OPO's DSA	<p><del>Priority 1, blood type compatible with the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li><u>At least 1 year old and blood type compatible with the donor</u></li> <li><u>At least 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	Zone A	At least 12 years old, blood type identical to the donor
8	Zone A	At least 12 years old, blood type compatible with the donor
9	Zone A	<p><del>Priority 1, blood type identical to the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li><u>Less than 12 years old and blood type identical to the donor</u></li> <li><u>Less than 1 year old and blood type compatible with the donor</u></li> <li><u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
10	Zone A	<p><del>Priority 1, blood type compatible with the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li>• <u>At least 1 year old and blood type compatible with the donor</u></li> <li>• <u>At least 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
11	Zone A	Priority 2, blood type identical to the donor
12	Zone A	Priority 2, blood type compatible with the donor
13	Zone B	At least 12 years old, blood type identical to the donor
14	Zone B	At least 12 years old, blood type compatible with the donor
15	Zone B	<p><del>Priority 1, blood type identical to the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li>• <u>Less than 12 years old and blood type identical to the donor</u></li> <li>• <u>Less than 1 year old and blood type compatible with the donor</u></li> <li>• <u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>

Classification	Candidates that are included within the:	And are:
16	Zone B	<p><del>Priority 1, blood type compatible with the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <p><u>At least 1 year old and blood type compatible with the donor</u></p> <p><u>At least 1 year old and eligible for intended blood group incompatible offers</u></p>
17	Zone B	Priority 2, blood type identical to the donor
18	Zone B	Priority 2, blood type compatible with the donor
19	Zone C	At least 12 years old, blood type identical to the donor
20	Zone C	At least 12 years old, blood type compatible with the donor
21	Zone C	<p><del>Priority 1, blood type identical to the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li>• <u>Less than 12 years old and blood type identical to the donor</u></li> <li>• <u>Less than 1 year old and blood type compatible with the donor</u></li> <li>• <u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
22	Zone C	<p><del>Priority 1, blood type compatible with the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <p><u>At least 1 year old and blood type compatible with the donor</u></p> <p><u>At least 1 year old and eligible for intended blood group incompatible offers</u></p>
23	Zone C	Priority 2, blood type identical to the donor
24	Zone C	Priority 2, blood type compatible with the donor
25	Zone D	At least 12 years old, blood type identical to the donor
26	Zone D	At least 12 years old, blood type compatible with the donor
27	Zone D	<p><del>Priority 1, blood type identical to the donor</del></p> <p>Priority 1 and <i>one</i> of the following:</p> <p><u>Less than 12 years old and blood type identical to the donor</u></p> <p><u>Less than 1 year old and blood type compatible with the donor</u></p> <p><u>Less than 1 year old and eligible for intended blood group incompatible offers</u></p>



Classification	Candidates that are included within the:	And are:
28	Zone D	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
29	Zone D	Priority 2, blood type identical to the donor
30	Zone D	Priority 2, blood type compatible with the donor
31	Zone E	At least 12 years old, blood type identical to the donor
32	Zone E	At least 12 years old, blood type compatible with the donor
33	Zone E	Priority 1, blood type identical to the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul>
34	Zone E	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
35	Zone E	Priority 2, blood type identical to the donor
36	Zone E	Priority 2, blood type compatible with the donor

#### **10.4.D Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old**

Single and double lungs from deceased donors at least 12 years old to less than 18 years old are allocated according to *Table 10-6* below.

**Table 10-6: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old**

Classification	Includes Candidates that are within the:	And are:
4	OPO's DSA	12 to less than 18 years old, blood type identical to the donor
2	OPO's DSA	12 to less than 18 years old, blood type compatible with the donor

<b>Classification</b>	<b>Includes Candidates that are within the:</b>	<b>And are:</b>
<b>3</b>	OPO's DSA	Priority 1, blood type identical to the donor
<b>4</b>	OPO's DSA	Priority 1, blood type compatible with the donor
<b>5</b>	OPO's DSA	Priority 2, blood type identical to the donor
<b>6</b>	OPO's DSA	Priority 2, blood type compatible with the donor
<b>7</b>	OPO's DSA	At least 18 years old, blood type identical to the donor
<b>8</b>	OPO's DSA	At least 18 years old, blood type compatible with the donor
<b>9</b>	Zone A	12 to less than 18 years old, blood type identical to the donor
<b>10</b>	Zone A	12 to less than 18 years old, blood type compatible with the donor
<b>11</b>	Zone A	Priority 1, blood type identical to the donor
<b>12</b>	Zone A	Priority 1, blood type compatible with the donor
<b>13</b>	Zone A	Priority 2, blood type identical to the donor
<b>14</b>	Zone A	Priority 2, blood type compatible with the donor
<b>15</b>	Zone A	At least 18 years old, blood type identical to the donor
<b>16</b>	Zone A	At least 18 years old, blood type compatible with the donor
<b>17</b>	Zone B	12 to less than 18 years old, blood type identical to the donor
<b>18</b>	Zone B	12 to less than 18 years old, blood type compatible with the donor
<b>19</b>	Zone B	Priority 1, blood type identical to the donor
<b>20</b>	Zone B	Priority 1, blood type compatible with the donor
<b>21</b>	Zone B	Priority 2, blood type identical to the donor
<b>22</b>	Zone B	Priority 2, blood type compatible with the donor
<b>23</b>	Zone B	At least 18 years old, blood type identical to the donor
<b>24</b>	Zone B	At least 18 years old, blood type compatible with the donor
<b>25</b>	Zone C	12 to less than 18 years old, blood type identical to the donor
<b>26</b>	Zone C	12 to less than 18 years old, blood type compatible with the donor

<b>Classification</b>	<b>Includes Candidates that are within the:</b>	<b>And are:</b>
<b>27</b>	Zone C	Priority 1, blood type identical to the donor
<b>28</b>	Zone C	Priority 1, blood type compatible with the donor
<b>29</b>	Zone C	Priority 2, blood type identical to the donor
<b>30</b>	Zone C	Priority 2, blood type compatible with the donor
<b>31</b>	Zone C	At least 18 years old, blood type identical to the donor
<b>32</b>	Zone C	At least 18 years old, compatible with the donor
<b>33</b>	Zone D	12 to less than 18 years old, blood type identical to the donor
<b>34</b>	Zone D	12 to less than 18 years old, blood type compatible with the donor
<b>35</b>	Zone D	Priority 1, blood type identical to the donor
<b>36</b>	Zone D	Priority 1, blood type compatible with the donor
<b>37</b>	Zone D	Priority 2, blood type identical to the donor
<b>38</b>	Zone D	Priority 2, blood type compatible with the donor
<b>39</b>	Zone D	At least 18 years old, blood type identical to the donor
<b>40</b>	Zone D	At least 18 years old, blood type compatible with the donor
<b>41</b>	Zone E	12 to less than 18 years old, blood type identical to the donor
<b>42</b>	Zone E	12 to less than 18 years old, blood type compatible with the donor
<b>43</b>	Zone E	Priority 1, blood type identical to the donor
<b>44</b>	Zone E	Priority 1, blood type compatible with the donor
<b>45</b>	Zone E	Priority 2, blood type identical to the donor
<b>46</b>	Zone E	Priority 2, blood type compatible with the donor
<b>47</b>	Zone E	At least 18 years old, blood type identical to the donor
<b>48</b>	Zone E	At least 18 years old, blood type compatible with the donor

## 10.4.ED Allocation of Lungs from Deceased Donors Less than 4218 Years Old

Single and double lungs from deceased donors less than 4218 years old are allocated according to *Table 10-710* below.

**Table 10-710: Allocation of Lungs from Deceased Donors Less than 4218 Years Old**

Classification	Candidates that are included within the:	And are:
<b>1</b>	OPO's DSA, Zone A, or Zone B	<del>Priority 1, blood type identical to the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li><u>Less than 12 years old and blood type identical to the donor</u></li> <li><u>Less than 1 year old and blood type compatible with the donor</u></li> <li><u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<b>2</b>	OPO's DSA, Zone A, or Zone B	<del>Priority 1, blood type compatible with the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li><u>At least 1 year old and blood type compatible with the donor</u></li> <li><u>At least 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<b>3</b>	OPO's DSA, Zone A, or Zone B	Priority 2, blood type identical to the donor
<b>4</b>	OPO's DSA, Zone A, or Zone B	Priority 2, blood type compatible with the donor
<b>5</b>	OPO's DSA <sub>1</sub> or Zone A <sub>1</sub> or Zone B	12 to less than 18 years old, blood type identical to the donor
<b>6</b>	OPO's DSA <sub>1</sub> or Zone A <sub>1</sub> or Zone B	12 to less than 18 years old, blood type compatible with the donor
<b>7</b>	OPO's DSA	At least 18 years, blood type identical to the donor
<b>8</b>	OPO's DSA	At least 18 years, blood type compatible with the donor
<b>9</b>	Zone A	At least 18 years old, blood type identical to the donor
<b>10</b>	Zone A	At least 18 years old, blood type compatible with the donor
<del><b>11</b></del>	<del>Zone B</del>	<del>12 to less than 18 years old, blood type identical to the donor</del>
<del><b>12</b></del>	<del>Zone B</del>	<del>12 to less than 18 years old, blood type compatible with the donor</del>
<b>4311</b>	Zone B	At least 18 years old, blood type identical to the donor
<b>4412</b>	Zone B	At least 18 years old, blood type compatible with the donor

<b>Classification</b>	<b>Candidates that are included within the:</b>	<b>And are:</b>
<b><u>4513</u></b>	Zone C	<del>Priority 1, blood type identical to the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>• <u>Less than 12 years old and blood type identical to the donor</u></li> <li>• <u>Less than 1 year old and blood type compatible with the donor</u></li> <li>• <u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<b><u>4614</u></b>	Zone C	<del>Priority 1, blood type compatible with the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>• <u>At least 1 year old and blood type compatible with the donor</u></li> <li>• <u>At least 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<b><u>4715</u></b>	Zone C	Priority 2, blood type identical to the donor
<b><u>4816</u></b>	Zone C	Priority 2, blood type compatible with the donor
<b><u>4917</u></b>	Zone C	12 to less than 18 years old, blood type identical to the donor
<b><u>2018</u></b>	Zone C	12 to less than 18 years old, blood type compatible with the donor
<b><u>2419</u></b>	Zone C	At least 18 years old, blood type identical to the donor
<b><u>2220</u></b>	Zone C	At least 18 years old, blood type compatible with the donor
<b><u>2321</u></b>	Zone D	<del>Priority 1, blood type identical to the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>• <u>Less than 12 years old and blood type identical to the donor</u></li> <li>• <u>Less than 1 year old and blood type compatible with the donor</u></li> <li>• <u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<b><u>2422</u></b>	Zone D	<del>Priority 1, blood type compatible with the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>• <u>At least 1 year old and blood type compatible with the donor</u></li> <li>• <u>At least 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<b><u>2523</u></b>	Zone D	Priority 2, blood type identical to the donor
<b><u>2624</u></b>	Zone D	Priority 2, blood type compatible with the donor
<b><u>2725</u></b>	Zone D	12 to less than 18 years old, blood type identical to the donor

Classification	Candidates that are included within the:	And are:
<u>2826</u>	Zone D	12 to less than 18 years old, blood type compatible with the donor
<u>2927</u>	Zone D	At least 18 years old, blood type identical to the donor
<u>3028</u>	Zone D	At least 18 years old, blood type compatible with the donor
<u>3129</u>	Zone E	<del>Priority 1, blood type identical to the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>• <u>Less than 12 years old and blood type identical to the donor</u></li> <li>• <u>Less than 1 year old and blood type compatible with the donor</u></li> <li>• <u>Less than 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<u>3230</u>	Zone E	<del>Priority 1, blood type compatible with the donor</del> Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> <li>• <u>At least 1 year old and blood type compatible with the donor</u></li> <li>• <u>At least 1 year old and eligible for intended blood group incompatible offers</u></li> </ul>
<u>3331</u>	Zone E	Priority 2, blood type identical to the donor
<u>3432</u>	Zone E	Priority 2, blood type compatible with the donor
<u>3533</u>	Zone E	12 to less than 18 years old, blood type identical to the donor
<u>3634</u>	Zone E	12 to less than 18 years old, blood type compatible with the donor
<u>3735</u>	Zone E	At least 18 years old, blood type identical to the donor
<u>3836</u>	Zone E	At least 18 years old, blood type compatible with the donor

[Subsequent tables will be renumbered as necessary.]

### **5.3.E Pediatric Heart Acceptance Criteria to Receive Intended Blood Group Incompatible Hearts from Donors of Any Blood Type**

A transplant hospital may specify whether a candidate registered before two years of age is willing to accept a heart from an intended blood group incompatible deceased donor ~~of any blood type~~.

## **6.5 Heart Allocation Classifications and Rankings**

### **6.5.A Allocation of Hearts by Blood Type**

Within each heart status and geographical zone classification, hearts are first allocated to primary blood type candidates then to secondary blood type candidates according to the blood type matching requirements in Table 6-5 below:

**Table 6-5: Blood Type Matching Prioritization for Heart Allocation**

<b>Hearts from Deceased Donors with:</b>	<b>Are Allocated to Primary Candidates defined as:</b>	<b>Then to Secondary Candidates, defined as:</b>
<b>Blood Type O</b>	Blood type O <i>or</i> blood type B	Blood type A or blood type AB
<b>Blood Type A</b>	Blood type A or blood type AB	Not applicable
<b>Blood Type B</b>	Blood type B or blood type AB	Not applicable
<b>Blood Type AB</b>	Blood type AB	Not applicable

Pediatric candidates that are less than one year old at the time of the match run, including candidates ~~qualified~~ eligible to receive a heart from an intended blood group incompatible deceased donor ~~of any blood type~~, will be classified as a primary blood type match candidate.

Pediatric candidates that are at least one year of age at the time of the match run but registered before their second birthday and are eligible to receive a heart from an intended blood group incompatible deceased donor ~~of any blood type~~ will be classified as a secondary blood type match candidate, unless they are a primary blood type match candidate according to *Table 6-5*.

### **6.5.B Eligibility for Intended Blood Group Incompatible Heart Offers from Deceased Donors of Any Blood Type Hearts**

The candidate will be eligible for intended blood group incompatible heart offers ~~from deceased donors of any blood type~~ if the candidate meets at least *one* of the following conditions:

Candidate is less than one year old at the time of the match run, and meets both of the following:

- a. Is registered as status 1A or 1B.
- b. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.

Candidate is at least one year old at the time of the match run, and meets all of the following:

- a. Is registered prior to turning two years old.
- b. Is registered as status 1A or 1B.
- c. Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

Accurate isohemagglutinin titers must be reported for candidates eligible to accept an intended blood group incompatible heart ~~from a deceased donor of any blood type~~ according to Table 6-6 below, at *all* of the following times:

1. Upon initially ~~indicating~~ reporting that a candidate is willing to accept an intended blood group incompatible heart ~~from a deceased donor of any blood type~~.

2. Every 30 days after initially ~~indicating reporting that~~ a candidate is willing to accept an intended blood group incompatible heart ~~from a deceased donor of any blood type.~~

**Table 6-6: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Heart**

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:
A	Anti-B
B	Anti-A
O	Anti-A and Anti-B

Accurate isohemagglutinin titers ~~will~~ must be reported for recipients of ~~a heart with an intended incompatible blood type heart,~~ according to Table 6-7, as follows:

1. At transplant from a blood sample taken within 24 hours prior to transplant.
2. If graft loss occurs within one year after transplant from the most recent blood sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

**Table 6-7: Isohemagglutinin Titer Reporting Requirements for a Recipient of ~~a Heart from a Donor with an Intended Blood Group Incompatible Heart Blood Type~~**

Deceased donor's blood type:	Recipient's blood type:	Isohemagglutinin titer reporting requirement:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report to the OPTN Contractor the highest titer value.

**Table 6-8: Allocation of Hearts from Deceased Donors At Least 18 Years Old**

Classification	Candidates that are within the:	And are:
<b>1</b>	OPO's DSA	Adult or pediatric status 1A and primary blood type match with the donor
<b>2</b>	OPO's DSA	Adult or pediatric status 1A and secondary blood type match with the donor
<b>3</b>	OPO's DSA	Adult or pediatric status 1B and primary blood type match with the donor
<b>4</b>	OPO's DSA	Adult or pediatric status 1B and secondary blood type match with the donor
<b>5</b>	Zone A	Adult or pediatric status 1A and primary



		blood type match with the donor
<b>6</b>	Zone A	Adult or pediatric status 1A and secondary blood type match with the donor
<b>7</b>	Zone A	Adult or pediatric status 1B and primary blood type match with the donor
<b>8</b>	Zone A	Adult or pediatric status 1B and secondary blood type match with the donor
<b>9</b>	OPO's DSA	Adult or pediatric status 2 and primary blood type match with the donor
<b>10</b>	OPO's DSA	Adult or pediatric Status 2 and secondary blood type match with the donor
<b>11</b>	Zone B	Adult or pediatric status 1A and primary blood type match with the donor
<b>12</b>	Zone B	Adult or pediatric status 1A and secondary blood type match with the donor
<b>13</b>	Zone B	Adult or pediatric status 1B and primary blood type match with the donor
<b>14</b>	Zone B	Adult or pediatric status 1B and secondary blood type match with the donor
<b>15</b>	Zone A	Adult or pediatric status 2 and primary blood type match with the donor
<b>16</b>	Zone A	Adult or pediatric status 2 and secondary blood type match with the donor
<b>17</b>	Zone B	Adult or pediatric status 2 and primary blood type match with the donor
<b>18</b>	Zone B	Adult or pediatric status 2 and secondary blood type match with the donor
<b>19</b>	Zone C	Adult or pediatric status 1A and primary blood type match with the donor
<b>20</b>	Zone C	Adult or pediatric status 1A and secondary blood type match with the donor
<b>21</b>	Zone C	Adult or pediatric status 1B and primary blood type match with the donor
<b>22</b>	Zone C	Adult or pediatric status 1B and secondary blood type match with the donor
<b>23</b>	Zone C	Adult or pediatric status 2 and primary blood type match with the donor
<b>24</b>	Zone C	Adult or pediatric status 2 and secondary blood type match with the donor
<b>25</b>	Zone D	Adult or pediatric status 1A and primary blood type match with the donor
<b>26</b>	Zone D	Adult or pediatric status 1A and secondary blood type match with the donor
<b>27</b>	Zone D	Adult or pediatric status 1B and primary blood type match with the donor
<b>28</b>	Zone D	Adult or pediatric status 1B and secondary blood type match with the donor

<b>29</b>	Zone D	Adult or pediatric status 2 and primary blood type match with the donor
<b>30</b>	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
<b>31</b>	Zone E	Adult or pediatric status 1A and primary blood type match with the donor
<b>32</b>	Zone E	Adult or pediatric status 1A and secondary blood type match with the donor
<b>33</b>	Zone E	Adult or pediatric status 1B and primary blood type match with the donor
<b>34</b>	Zone E	Adult or pediatric status 1B and secondary blood type match with the donor
<b>35</b>	Zone E	Adult or pediatric status 2 and primary blood type match with the donor
<b>36</b>	Zone E	Adult or pediatric status 2 and secondary blood type match with the donor

### 6.5.E Allocation of Hearts from Donors Less Than 18 Years Old

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-9* below.

**Table 6-9: Allocation of Hearts from Donors Less Than 18 Years Old**

<b>Classification</b>	<b>Candidates that are within the:</b>	<b>And are:</b>
<b>1</b>	OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor
<b>2</b>	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
<b>3</b>	OPO's DSA	Adult status 1A and primary blood type match with the donor
<b>4</b>	OPO's DSA	Adult status 1A and secondary blood type match with the donor
<b>5</b>	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor
<b>6</b>	OPO's DSA or Zone A	Pediatric Status 1B and secondary blood type match with the donor
<b>7</b>	OPO's DSA	Adult Status 1B and primary blood type match with the donor
<b>8</b>	OPO's DSA	Adult Status 1B and secondary blood type match with the donor
<b>9</b>	Zone A	Adult Status 1A and primary blood type match with the donor
<b>10</b>	Zone A	Adult Status 1A and secondary blood type match with the donor
<b>11</b>	Zone A	Adult Status 1B and primary blood type match with the donor

<b>Classification</b>	<b>Candidates that are within the:</b>	<b>And are:</b>
<b>12</b>	Zone A	Adult Status 1B and secondary blood type match with the donor
<b>13</b>	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
<b>14</b>	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
<b>15</b>	OPO's DSA	Adult status 2 and primary blood type match with the donor
<b>16</b>	OPO's DSA	Adult status 2 and secondary blood type match with the donor
<b>17</b>	Zone B	Pediatric status 1A and primary blood type match with the donor
<b>18</b>	Zone B	Pediatric status 1A and secondary blood type match with the donor
<b>19</b>	Zone B	Adult status 1A and primary blood type match with the donor
<b>20</b>	Zone B	Adult status 1A and secondary blood type match with the donor
<b>21</b>	Zone B	Pediatric status 1B and primary blood type match with the donor
<b>22</b>	Zone B	Pediatric status 1B, secondary blood type match with the donor
<b>23</b>	Zone B	Adult status 1B and primary blood type match with the donor
<b>24</b>	Zone B	Adult status 1B and secondary blood type match with the donor
<b>25</b>	Zone A	Pediatric status 2 and primary blood type match with the donor
<b>26</b>	Zone A	Pediatric status 2 and secondary blood type match with the donor
<b>27</b>	Zone A	Adult status 2 and primary blood type match with the donor
<b>28</b>	Zone A	Adult status 2 and secondary blood type match with the donor
<b>29</b>	Zone B	Pediatric status 2, primary blood type match with the donor
<b>30</b>	Zone B	Pediatric status 2 and secondary blood type match with the donor
<b>31</b>	Zone B	Adult status 2 and primary blood type match with the donor
<b>32</b>	Zone B	Adult status 2 and secondary blood type match with the donor
<b>33</b>	Zone C	Pediatric status 1A and primary blood type match with the donor

<b>Classification</b>	<b>Candidates that are within the:</b>	<b>And are:</b>
<b>34</b>	Zone C	Pediatric status 1A and secondary blood type match with the donor
<b>35</b>	Zone C	Adult status 1A and primary blood type match with the donor
<b>36</b>	Zone C	Adult status 1A and secondary blood type match with the donor
<b>37</b>	Zone C	Pediatric status 1B and primary blood type match with the donor
<b>38</b>	Zone C	Pediatric status 1B and secondary blood type match with the donor
<b>39</b>	Zone C	Adult status 1B and primary blood type match with the donor
<b>40</b>	Zone C	Adult status 1B and secondary blood type match with the donor
<b>41</b>	Zone C	Pediatric status 2 and primary blood type match with the donor
<b>42</b>	Zone C	Pediatric status 2 and secondary blood type match with the donor
<b>43</b>	Zone C	Adult status 2 and primary blood type match with the donor
<b>44</b>	Zone C	Adult status 2 and secondary blood type match with the donor
<b>45</b>	Zone D	Pediatric status 1A and primary blood type match with the donor
<b>46</b>	Zone D	Pediatric status 1A and secondary blood type match with the donor
<b>47</b>	Zone D	Adult status 1A and primary blood type match with the donor
<b>48</b>	Zone D	Adult status 1A and secondary blood type match with the donor
<b>49</b>	Zone D	Pediatric status 1B and primary blood type match with the donor
<b>50</b>	Zone D	Pediatric status 1B and secondary blood type match with the donor
<b>51</b>	Zone D	Adult status 1B and primary blood type match with the donor
<b>52</b>	Zone D	Adult status 1B and secondary blood type match with the donor
<b>53</b>	Zone D	Pediatric status 2 and primary blood type match with the donor
<b>54</b>	Zone D	Pediatric status 2 and secondary blood type match with the donor
<b>55</b>	Zone D	Adult status 2 and primary blood type match with the donor

<b>Classification</b>	<b>Candidates that are within the:</b>	<b>And are:</b>
<b>56</b>	Zone D	Adult status 2 and secondary blood type match with the donor
<b>57</b>	Zone E	Pediatric status 1A and primary blood type match with the donor
<b>58</b>	Zone E	Pediatric status 1A and secondary blood type match with the donor
<b>59</b>	Zone E	Adult status 1A and primary blood type match with the donor
<b>60</b>	Zone E	Adult status 1A and secondary blood type match with the donor
<b>61</b>	Zone E	Pediatric status 1B and primary blood type match with the donor
<b>62</b>	Zone E	Pediatric status 1B and secondary blood type match with the donor
<b>63</b>	Zone E	Adult status 1B and primary blood type match with the donor
<b>64</b>	Zone E	Adult status 1B and secondary blood type match with the donor
<b>65</b>	Zone E	Pediatric status 2 and primary blood type match with the donor
<b>66</b>	Zone E	Pediatric status 2 and secondary blood type match with the donor
<b>67</b>	Zone E	Adult status 2 and primary blood type match with the donor
<b>68</b>	Zone E	Adult status 2 and secondary blood type match with the donor
<b>69</b>	OPO's DSA or Zone A	<del>Pediatric status 1A and blood type incompatible with the donor</del>
<b>70</b>	OPO's DSA or Zone A	<del>Pediatric status 1B and blood type incompatible with the donor</del>
<b>71</b>	OPO's DSA	<del>Pediatric status 2 and blood type incompatible with the donor</del>
<b>72</b>	Zone B	<del>Pediatric status 1A and blood type incompatible with the donor</del>
<b>73</b>	Zone B	<del>Pediatric status 1B and blood type incompatible with the donor</del>
<b>74</b>	Zone C	<del>Pediatric status 1A and blood type incompatible with the donor</del>
<b>75</b>	Zone C	<del>Pediatric status 1B and blood type incompatible with the donor</del>
<b>76</b>	Zone D	<del>Pediatric status 1A and blood type incompatible with the donor</del>
<b>77</b>	Zone D	<del>Pediatric status 1B and blood type incompatible with the donor</del>

Classification	Candidates that are within the:	And are:
<b>78</b>	<del>Zone E</del>	<del>Pediatric status 1A and blood type incompatible with the donor</del>
<b>79</b>	<del>Zone E</del>	<del>Pediatric status 1B and blood type incompatible with the donor</del>

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