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9 **UNITED STATES BANKRUPTCY COURT**  
10 **CENTRAL DISTRICT OF CALIFORNIA**  
11 **LOS ANGELES DIVISION**

12 In re: ) Lead Case No.: 2:18-bk-20151-ER

13 )  
14 ) Jointly Administered With:  
15 **VERITY HEALTH SYSTEM OF** ) Case No.: 2:18-bk-20162-ER;  
16 **CALIFORNIA, INC. et al.,** ) Case No.: 2:18-bk-20163-ER;  
17 ) Case No.: 2:18-bk-20164-ER;  
18 Debtor(s). ) Case No.: 2:18-bk-20165-ER;  
19 ) Case No.: 2:18-bk-20167-ER;  
20 ) Case No.: 2:18-bk-20168-ER;  
21 ) Case No.: 2:18-bk-20169-ER;  
22 ) Case No.: 2:18-bk-20171-ER;  
23 ) Case No.: 2:18-bk-20172-ER;  
24 ) Case No.: 2:18-bk-20173-ER;  
25 ) Case No.: 2:18-bk-20175-ER;  
26 ) Case No.: 2:18-bk-20176-ER;  
27 ) Case No.: 2:18-bk-20178-ER;  
28 ) Case No.: 2:18-bk-20179-ER;  
29 ) Case No.: 2:18-bk-20180-ER;  
30 ) Case No.: 2:18-bk-20181-ER

- 31  Affects All Debtors )
- 32  Affects Verity Health System of )
- 33 California, Inc. )
- 34  Affects O'Connor Hospital )
- 35  Affects Saint Louise Regional Hospital )
- 36  Affects St. Francis Medical Center )
- 37  Affects St. Vincent Medical Center )
- 38  Affects Seton Medical Center )
- 39  Affects O'Connor Hospital Foundation )
- 40  Affects Saint Louise Regional Hospital )
- 41 Foundation )
- 42  Affects St. Francis Medical Center of )
- 43 Lynwood Foundation )
- 44  Affects St. Vincent Foundation )
- 45  Affects St. Vincent Dialysis Center, Inc. )
- 46  Affects Seton Medical Center )
- 47 Foundation )
- 48  Affects Verity Business Services )
- 49  Affects Verity Medical Foundation )
- 50  Affects Verity Holdings, LLC )
- 51  Affects De Paul Ventures, LLC )
- 52  Affects De Paul Ventures – San Jose )
- 53 Dialysis, LLC )

Chapter 11 Cases

**SUBMISSION OF SEVENTH REPORT  
BY PATIENT CARE OMBUDSMAN,  
JACOB NATHAN RUBIN, MD, FACC,  
PURSUANT TO 11 U.S.C. § 333(b)(2)**

[NO HEARING REQUIRED]

Debtors and Debtors In Possession )



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1 Jacob Nathan Rubin, MD, FAAC, the Patient Care Ombudsman (“PCO”) appointed under  
2 11 U.S.C. § 333 in the above-referenced chapter 11 bankruptcy cases of the affected debtors and  
3 debtors in possession (collectively, “Debtors”), hereby submits his seventh report (“Report”) to the  
4 Court pursuant to 11 U.S.C. § 333(b) regarding the quality of patient care provided to patients of  
5 the affected Debtors. The Report is hereby attached as Exhibit A.

6 Submitted by:

7 LEVENE, NEALE, BENDER, YOO & BRILL L.L.P.  
8

9 By: /s/ Ron Bender

10 RON BENDER

11 MONICA Y. KIM

12 Attorneys for Patient Care Ombudsman  
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**II. VERITY SITES REVIEWED BY THE PCO**

As a matter of reference, the Debtors have transferred operations of O'Connor and St. Louise Medical Centers to Santa Clara County. In addition, the Medical Clinics and Urgent Care Centers have closed or transferred operations to other entities. The medical records of all the patients have gone to the separate entities or with the individual physicians except for Sport Orthopedic and Rehabilitation (SOAR).

In the case of SOAR, the Debtors are the custodian of medical records. As indicated to the PCO, the Debtors will remain as custodian of the medical records until the patients' physicians take control of the medical records.

Debtors continue to operate four acute care hospital centers and one hemodialysis center. Debtors' maintain facilities in Northern and Southern California. These include the following:

A. HOSPITALS (4)

St. Vincent's Medical Center

St. Francis Medical Center

Seton Coastside

Seton Medical Center

B. DIALYSIS CENTER (1)

St. Vincent's Dialysis Center

**III. METHODOLOGY AND MEDICAL STANDARD APPLIED BY THE PCO**

The PCO continues to monitor patient care provided by the Debtors by applying the principles and structure of evidence-based review outlined in the PCO's first Report.

**A. Seventh Report Review Strategy**

The PCO continued to address and review previous ongoing items of concern and maintain appropriate follow-up. Since the last PCO report, significant patient care related events have

1 developed and been identified by CMS, through the diligent reporting of events to the PCO by  
2 administration and Dr. Del Junco, CMO. (See Conclusions).

3  
4 The concentration of this Report will specifically address the suspension of St. Vincent's  
5 Medical Center Liver Transplant Service and the impact of the suspension on patient care.  
6 Transplanted patients, patients on the transplant waitlist and patients referred to the liver transplant  
7 service all need to be transitioned to an UNOS approved liver transplant center.

8 The PCO spent the last 4 months investigating the potential suspension of SVMC's Liver  
9 Transplant Service and the potential patient harm inherent in the suspension. This included  
10 attending the SVMC public hearing, multiple discussions with administration, communication with  
11 the Debtors' attorneys and Assistant Attorney General's Office.

12  
13 The PCO continues to communicate frequently, either telephonically or via on-site visits,  
14 with Dr. Del Junco, CMO and Margaret Peterson, CEO of SVMC.

15 In addition, the PCO was well-informed on the status of all events (positive or negative),  
16 corrective action plan progress, results of CDPH investigations, and State Board of Pharmacy and  
17 Joint Commission surveys.

18 The diligence of the Debtors to manage the E-Data room punctually assisted the PCO in  
19 performing his duties. In addition, professional relationships with administrative and medical staff  
20 have developed with the PCO that encourage contemporaneous exchange of information allowing  
21 the PCO to address problems and collaboratively develop solutions with the Debtors' management  
22 team in real time.  
23

24 **B. Documents Reviewed in Data Room (One Drive) and at Debtors' Locations.**

25 The data room documents were requested from Debtors and could only be reviewed in read  
26 only format. The following items will continue to be included in our evaluation process:  
27

28 CALL PANEL

1 CDPH-California Department of Public Health reports

2 CMS-deemed status report

3 JOINT COMMISSION SURVEY

4 MEDICAL EXECUTIVE COMMITTEE (MEC)

5 PHARMACY SHORTAGE

6 PROFESSIONAL LIABILITY (settled and pending)

7 QUALITY ASSURANCE PERFORMANCE IMPROVEMENT COMMITTEE

8 MINUTES

9 RISK MANAGEMENT DATA

10 VENDORS

11 LEAPFROG DATA

12 CALIFORNIA STATE BOARD OF PHARMACY SURVEY

13 **IV. REVIEW OF DEBTORS BY INDIVIDUAL LOCATION**

14 **1. HOSPITALS**

15 **2. St. Vincent's Medical Center (SVMC)**

16 **a. Site Visit**

17 **i. CMS Validation Survey**

18 Centers for Medicare and Medicaid services (CMS) performed a hospital wide survey on  
19 July 8, 2019, that continued thru July 11, 2019, in response to a complaint filed by SVMC  
20 regarding an abrupt higher than normal rate of surgical infections.  
21  
22

23 The findings of the CMS validation survey reflect the findings of the California Department  
24 of Public Health, licensing and certification, during a complaint validation survey for complaint  
25 number CA 00640313.  
26  
27  
28

1 The survey covered the breach in numerous mandated requirements for Conditions of  
2 Participation (COP).

3 The review of surgical services, infection control, nursing services, quality assurance,  
4 performance improvement and Governing Board responsibilities pertaining to the COP.

5 The survey deficiencies and action plans were carefully reviewed by the PCO.

6 On September 25<sup>th</sup>, 2019, CDPH performed a revisit to validate the implementation of the  
7 action plans that were offered for each deficiency. Following the visit, SVMC received a letter  
8 from CDPH confirming compliance with federal regulations COP related to the deficiencies  
9 observed during the initial survey.  
10

#### 11 **ii. Leapfrog and HCAHPS**

12 During the on-site visit, the PCO and administration discussed progress on clinical quality  
13 measures. Many of the variables that contribute to scoring relate to an electronic medical record  
14 system that the current healthcare system is lacking.  
15

16 The PCO discussed Leapfrog Data with administration in detail. The overall acquired  
17 infection rates remain low. The infection rates in the area of Central Line Acquired Infections  
18 (CLAI) vary between the facilities. Administration continues to aggressively monitor and act on  
19 any increase in CLAI.

#### 20 **iii. Liver Transplant Unit**

##### 21 **Background**

22 Since the last report, the PCO verified that SVMC submitted the appropriate documents to  
23 terminate the SVMC Liver Transplant program in accordance with Organ Procurement and  
24 Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS) regulations.  
25 Transplant programs are governed by the authority and jurisdictions of OPTN and UNOS.  
26  
27  
28

1 SVMC Liver Transplant Program and clinic have suspended accepting and evaluating any  
2 further patients.

3 OPTN bylaws require institutions to follow detailed steps when terminating transplant  
4 programs to certified accepting centers to safeguard a smooth disposition and transition of patients.

5 OPTN is a public-private network that provides a link between all professionals involved in  
6 the United States organ donation and transplantation system.

7 UNOS is a private, non-for-profit organization under contract with the Health Resources  
8 and Services Administration (HRSA) of the U.S. Department of Health and Human Services  
9 (DHHS) and serves as the OPTN.

10 The patients are a third-party beneficiary of the agreement between these organizations and  
11 the center (specifically SVMC).

12 St. Vincent's Medical Center Liver Transplant Service provides services for a vulnerable  
13 population of patients that have difficulties in access to care. The population of patients that reside  
14 in the catchment area of St. Vincent's Medical Center are of lower socioeconomic status,  
15 predominantly utilize Medicaid services for their health care, and are often immigrants with limited  
16 access to care and English language skills.

17 The current liver transplant centers in the Los Angeles area have a difficult time serving the  
18 current needs of the population. Wait times are long, and patients often succumb while waiting to  
19 be seen, or are delayed so long that transplant is no longer an option. The SVMC liver transplant  
20 service was developed to help serve these patients. Many of these patients do not have the logistic  
21 capability of reaching other liver transplant centers in the area, even if they could get an  
22 appointment. Thus, the liver transplant service was adopted by St. Vincent's Medical Center to  
23 provide needed services to the community, add value to the business model of the hospital, and to  
24 establish a center for clinical excellence.

1 The PCO strongly believes that the transfer of care, following the OPTN bylaws required  
2 that the transfer of care must be in place before completion of the sale of the hospital unless the  
3 responsibility is assumed by the buyer.

4 The specific section in the OPTN bylaws referencing patient disposition regulations are  
5 defined in Appendix K of the OPTN bylaws outlined below (Organ Procurement and  
6 Transplantation Network. OPTN bylaws appendix K. May 14, 2019. Available  
7 at: [https://optn.transplant.hrsa.gov/media/1201/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf), Accessed on October 3, 2019.)  
8

9 ***OPTN Appendix K: Transplant Program Inactivity, Withdrawal, and Termination***

10 Appendix K OPTN bylaws defines and outlines the operational obligations that transplant  
11 programs are required to follow to remain in compliance with OPTN and UNOS during inactivity,  
12 withdrawal or termination.

13 When accepting membership to OPTN, the member will comply with all of the OPTN  
14 obligations that include:

- 15 1. Applicable provisions of the:
- 16 a. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*
  - 17 b. OPTN Final Rule, 42 CFR Part 121
  - 18 c. OPTN Bylaws
  - 19 d. OPTN Policies
- 20
- 21 2. Acting to avoid risks to patient health or public safety
- 22
- 23 3. Fulfilling all requests for information

24 **K.1 Transplant Program Inactivity**

25 Upon knowledge that a program is unable to provide services, the members are required to  
26 provide official notice to OPTN/UNOS defining the temporal nature of the inactivity, withdrawal or  
27 termination. **This was completed by SVMC.**

28

1 A member can inactivate a program for several reasons including program termination  
2 associated with the inability to financially sustain the service line.

3 Programs are required to notify all patients enrolled in the transplant program, including:

- 4 • Potential candidates, including those currently in the referral for evaluation process.
- 5 • All candidates registered on the waiting list.
- 6 • Potential living donors, including those currently in the referral process, and the  
7 evaluation process, or awaiting donation.

8  
9 **This was completed by SVMC.**

10 **K.2 and K.3 Short-term Inactive Transplant Program Status and Long-term Inactive**  
11 **Transplant Program Status**

12 This section addresses programs that choose to place their program on short-term or long-  
13 term inactive status. **Not applicable to SVMC.**

14 **K.4 Withdrawal or Termination of Designated Transplant Program Status**

15 This section of the appendix is designated for those programs that *withdrawal or terminate*  
16 transplant designation status.

17  
18 **SVMC provided written notice to OPTN** regarding its voluntary termination of the  
19 transplant program which is then registered with the Secretary of Health and Human Services.

20 The written notice should be performed within 30 days of the intent to withdrawal  
21 designated transplant program status. **SVMC was compliant in the written notice to UNOS.**

22  
23 Following the voluntary withdrawal as a designated transplant program, the member **must**  
24 assist candidates in transferring to another transplant program. The transplant hospital **must**  
25 provide written notice to potential candidates, recipients, and living donors currently receiving care.

26 Specific notification delivery guidelines include commercial overnight delivery service,  
27 secure electronic communications, and registered or certified mail, with return receipt requested.

28

1 The written notice must be provided no later than seven days following withdrawal or  
2 termination and include the following content:

- 3 1. The reasons for loss of designated transplant program status.
- 4 2. Explanation that although the patient is still on the waiting list, the candidate  
5 cannot receive an organ offer through this program.
- 6 3. Options for potential candidates, recipients, and living donors to transfer to  
7 another transplant program.
- 8 4. Prior to being registered as an active candidate at another transplant program,  
9 the accepting transplant program will complete an evaluation to determine  
10 suitability for registration.
- 11 5. The phone number of the programs administrative office that can help with  
12 transferring the candidate or potential candidate to another program.
- 13 6. The transplant program must provide to UNOS a sample of each type of  
14 patient notice it sends to potential candidates, recipients and living donors  
15 along with a list of patients who receive the notice.  
16  
17

18 During the site visit on October 23<sup>rd</sup>, 2019, the PCO was verbally informed and guaranteed,  
19 by Margaret Peterson, CEO and Dr. Del Junco, CMO, that the Liver Transplant Program at SVMC  
20 has complied and is in compliance with the directives set forth in K.4 (Directives for official  
21 notification of potential candidates, recipients, and living donors).  
22

23 Thus, SVMC is performing diligently and exhaustively while working with the PCO to  
24 satisfy the safe transfer of the Liver Transplant Program patients to a certified transplant center, the  
25 result of which will be, not jeopardizing the kidney and pancreas transplant program UNOS status,  
26 as well.  
27  
28

1 SVMC administration created a list of Liver Transplant patients (Transplanted, Waitlisted  
2 and Referral) with their current transfer disposition, and this list was made available to the PCO  
3 (List attached as an exhibit). The list is updated and distributed to the PCO for review and  
4 discussion with SVMC administration and Dr. Del Junco.

5 As per regulations, UNOS requires updates on the progress of patient transition to certified  
6 transplant programs. With each update, the PCO telephonically or personally meets with  
7 administration to discuss the progress of the transfer plans.  
8

9 **K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal**

10 *“When a member transplant hospital experiences long-term inactivity, withdraws its*  
11 *designated transplant program status, or its designated transplant program status is*  
12 *terminated, it **must** (emphasis added):*

- 13 1. *Immediately suspend organ transplantation for the transplant program.*  
14 **(Completed by SVMC)**
  - 15 2. *Assist potential candidates and candidates in transferring to other*  
16 *designated transplant programs. **(Completed by SVMC)***
  - 17 3. *Provide a list to the OPTN Contractor of all of the transplant program’s*  
18 *candidates on the waiting list at the time of long-term inactivity,*  
19 *withdrawal, or termination and update it throughout this process. The*  
20 *program should indicate on the list of each candidate if: **(Completed by***  
21 *SVMC)*
- 22 • *A candidate or potential candidate chooses not to transfer to an alternative*  
23 *transplant program, provide the reason and indicate whether the candidate has been*  
24 *completely informed of the implications of this decision before they are removed*  
25 *from the waiting list.*
  - 26 • *A candidate or potential candidate chooses to transfer, indicate the transplant*  
27 *program to which the candidate is transferring. Periodic status updates will be*  
28 *required that documents each candidate’s transfer progress until the candidate is*  
*evaluated and accepted on the waiting list by another transplant program or*  
*removed from the waiting list.*
- a. *Expedite removal of all candidates from the transplant program’s waiting list, or, if*  
*the patient requests, transfer the candidate to another OPTN member transplant*  
*hospital.*
  - b. *Initiate transfer of all active candidates hospitalized at the transplant program to an*  
*accepting transplant hospital within 7 days of long-term inactivity, withdrawal, or*  
*termination. The transplant program **must** (emphasis added) complete the transfer*  
*process within 14 days unless transfer would be unsafe or discharge is anticipated*  
*within that time, or circumstances outside of the program’s control exist that prevent*  
*transfer within 14 days. The program must document and submit to the OPTN*  
*contractor all efforts to transfer its hospitalized candidates, if it is unable to meet*  
*these time periods. **(Completed by SVMC)***

1 c. *Provide a priority list of the most urgent candidates listed at the transplant program*  
2 *with an individualized plan of transfer, potential alternative transplant programs,*  
3 *and a timeline for transferring these candidates according to the following*  
4 *priorities:*

5 *For liver candidates, all Status 1A and 1B candidates must be transferred within 7*  
6 *days of long-term inactivity, withdrawal, or termination, followed by all active*  
7 *candidates in descending MELD/PELD score order, with all candidates whose*  
8 *MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all*  
9 *inactive candidates.*

10 *All active candidates should be transferred within 60 days of long-term inactivity,*  
11 *withdrawal, or termination without considering these guidelines.*

- 12 • *The program **must** (emphasis added) document and submit to the OPTN Contractor*  
13 *all efforts made for transfer of its candidates if it is unable to meet these deadlines.*
- 14 • *Document all efforts to transfer candidates to an alternative designated transplant*  
15 *program including all contacts made to facilitate the transfer of candidates.*
- 16 • *Remove every transplant candidate from the transplant program's waiting list within*  
17 *12 months of the program's long-term inactivity, withdrawal, or termination date.*

18 *A member that experiences long-term inactivity, withdrawal, or termination of a*  
19 *designated transplant program can temporarily provide care to transplant*  
20 *candidates and provide follow-up care as necessary to transplant recipients and*  
21 *living donors. Should the transplant program continue to provide follow-up care to*  
22 *transplant recipients and living donors, the program **must** (emphasis added)*  
23 *continue to submit OPTN follow up forms through UNetSM. Alternatively,*  
24 *transplant recipients may transfer care to another hospital.”*

25 **The buyer is not assuming this responsibility; therefore the Debtors must provide or**  
26 **contract for the services before the sale.**

#### 27 **K.6 Transferred Candidates Waiting Time**

28 Candidates that are eligible and accepted by UNOS qualified transplant centers will retain  
existing waiting times and continue to accrue waiting time according to their status on the waiting  
list at the time of the program's termination as a designated transplant program.

The candidate's time credit will be listed and forwarded to the new transplant program in  
order to maintain continuity of care.

This section is particularly of interest to the PCO and has been discussed at length with  
SVMC administration and Dr. Del Junco. The PCO regards this section requirements as a concrete

1 mechanism that provides terminal disposition documentation, thus finalizing the safe transfer of  
2 patients to an accepting transplant center.

3 SVMC, as the transferring transplant program, **must** complete all the following before a  
4 collective transfer is completed.

5 SVMC, per UNOC, **must** complete all the following requirements before the collective  
6 transfer of care is complete:

- 7
- 8 1. *“All required patient notifications according to Section K.3: Long-term Inactive*  
9 *Transplant Program Status or Section K.4: Withdrawal or Termination of*  
10 *Designated Transplant Program Status.*
  - 11 2. **A written agreement with each accepting transplant program that includes all of**  
12 **the following** (emphasis added):
    - 13 a. *Request for collective transfer of candidates’ waiting times*
    - 14 b. *List of patient names and identifiers to be transferred*
    - 15 c. *Mutually agreed upon transfer date*
    - 16 d. *Assurance of notification and patient consent to transfer according to Section*  
17 *K.5: Transition Plan during Long-term Inactivity, Termination, or*  
18 *Withdrawal*
    - 19 e. *List of active candidates that the transferring program agrees to change to*  
20 *inactive status if requested by the accepting transplant program*
    - 21 f. *Acknowledgement that all patient information and records available to the*  
22 *OPTN Contractor will be transferred without modification*
    - 23 g. *Acknowledgement that the transplant program accepting the patients accepts*  
24 *responsibility for patient notification and management according to all*  
25 *applicable OPTN Policies and Bylaws*

19 *Each accepting transplant program **must** (emphasis added) develop and implement*  
20 *a plan that includes **all of the following** (emphasis added):*

- 21 1. *Procedure and timeline for reviewing the status on each collectively transferred*  
22 *candidate and amending this status as appropriate until an evaluation is completed*  
23 *in accordance with the accepting program’s selection and listing protocol.*
- 24 2. *If the transferred candidate’s status is changed from active to inactive as part of the*  
25 *collective transfer agreement or part of implementing the accepting transplant*  
26 *program’s plan, then the accepting transplant hospital must notify the candidate*  
27 *about the status change. The notification must include what the candidate must do to*  
28 *be considered for an active status at the accepting transplant program. The*  
*notification must be completed within 14 days after the collective transfer date or*  
*after the status change date if it occurs post-collective transfer as part of this plan.*
3. *Expected timeline for completing evaluations and subsequent waiting list status*  
*adjustments on collective transfer candidates according to the accepting program’s*  
*selection and listing protocol.*

1                   Upon receipt of the written agreement and plan, the OPTN Contractor will  
2                   review the information and provide an expected collective transfer completion date  
3                   to all the transplant programs involved. After the collective transfer process has  
4                   been completed, the OPTN Contractor will provide written notification to the  
5                   transplant programs.

6                   The accepting hospital must submit a progress report to the OPTN  
7                   Contractor that contains an update on the evaluation status of each collective  
8                   transfer candidate at day 90 following the collective transfer. The accepting hospital  
9                   must submit this report within 14 days after day 90 following the collective transfer.  
10                  Additional updates may be requested from the OPTN Contractor to monitor  
11                  progress until all collective transfer candidates are evaluated and accepted on the  
12                  waiting list by a transplant program or removed from the waiting list.

13                  If the transferring transplant program no longer qualifies as a designated  
14                  transplant program and does not complete the requirements according to Appendix  
15                  K, the OPTN Contractor may approve and complete a collective transfer of  
16                  candidates' registrations and waiting times if the accepting transplant program  
17                  requests in writing to complete the transfer."

#### 18                  **K.7 Laboratory Tests**

19                  The transplant program **is required** to continue treating and evaluating candidates during  
20                  the collective transfer to appropriate transplant centers. During the transition, laboratory tests, *i.e.*  
21                  immunosuppressant drug levels, and other evaluation schedules should be maintained.

22                  The Liver Transplant clinic was closed, and the clinic employees laid off in October, 2019. SVMC  
23                  administration explained to the PCO that Dr. Annamalai started an offsite clinic that performs  
24                  continuity of care on a select number of patients. The PCO is currently inquiring about the  
25                  continuity status of the other listed patients not followed by Dr. Annamalai. The PCO will continue  
26                  to closely follow SVMC's compliance for this requirement.

27                  SVMC, despite exhaustive efforts to abide by the transfer of care requirements, is **NOT in**  
28                  **compliance** with the collective transfer timeline as referenced above.

                The PCO has personally observed the diligence and commitment to comply with the  
collective transfer guidelines. The PCO has not observed any indication that the fall outs to the  
collective transfer guidelines is related to the finances of the Debtors influenced by the bankruptcy

1 proceedings. On the contrary, the PCO was informed that the organization has utilized authorized  
2 funds and increased workforce hours to comply with the UNOS collective transfer.

3 Nonetheless, the PCO has no evidence that the UNOS/OPTN requirements, to which the  
4 patients are third-party beneficiaries, have been strictly followed. There is no written confirmation  
5 of accepting centers.

6 **b. Review: California Department of Public Health Reports**

7 During the last PCO observation cycle, two self-reported CDPH complaints were filed.

8 A wound was discovered in a critically ill Intensive Care Unit patient. SVMC self-reported  
9 the event along with an action plan that was reviewed by the PCO and discussed with  
10 administration. The patient was subsequently discharged from the facility in good condition.

11 **c. Critical Vendor Evaluation**

12 All vendors are currently providing services and equipment under their contractual  
13 agreements. Critical vendors continue to operate and supply critical equipment to the hospital  
14 without delay.  
15

16 **d. Pharmacy Shortages**

17 All pharmacy shortages were reviewed and found to be unrelated to the bankruptcy or  
18 vendor contract termination. The shortages listed are consistent with national or local shortages.  
19

20 **e. Joint Commission Accreditation Report findings:**

21 The last certification from Joint Commission was performed and completed on January 8<sup>th</sup>,  
22 2019. There have not been any new events that triggered a follow-up visit from Joint Commission.  
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1           **2. St. Francis Medical Center (SFMC)**

2           SFMC administration and the PCO discussed the current operational status, CDPH events,  
3 and the most recent ACS Trauma Service certification survey. Administration verified that the  
4 current finances are not impacting patient care.

5           **a. California Department of Public Health**

6           The PCO will report on any new CDPH reports as they become available following an  
7 investigation.  
8

9           SFMC had several CDPH reports filed during this reporting cycle.

10           A stage three pressure wound was discovered during the treatment of a patient and  
11 appropriately reported to CDPH. SFMC performed the necessary investigations and performed re-  
12 education of the staff and ancillary services. The PCO discussed this case with administration and  
13 is confident that the occurrence of the event was unrelated to the finances of the Debtors.  
14

15           The second incident was a patient fall. The circumstances of the fall were unrelated to the  
16 actions of the staff. According to the report details, the patient placed new shoes on before  
17 ambulating on the unit. The investigation found that the patient was unfamiliar with her shoes  
18 causing her to lose her footing, resulting in a fall.

19           The PCO discussed the case with administration and reviewed the action plan. The PCO  
20 determined that the incident was unrelated to staffing deficiencies or finances of the Debtors.  
21

22           The third event was reported because a nurse provided the wrong discharge instructions to  
23 two different patients on day of discharge. The patients were called back and provided with  
24 accurate discharge instructions. Education was provided to the nurse and other staff as part of the  
25 action plan. The incident did not cause harm or delay patient care to the patients involved.

26           The PCO confirmed that nurse staffing ratios were in compliance in the time period  
27 surrounding the incident.  
28

1           **b. Trauma Certification**

2           SFMC is an integral part of the Los Angeles Trauma System that is monitored and certified  
3 by Los Angeles Emergency Services and the American College of Surgeons (ACS).

4           During the last reporting cycle, the PCO reported that ACS did not recertify SFMC as an  
5 ACS accredited Trauma Center.

6           ACS made several policy recommendations that SFMC implemented.

7           On November 7<sup>th</sup>, 2019, ACS performed a recertification and validation survey. According  
8 to administration, the survey was successful and SFMC expects to obtain a successful  
9 recertification and accreditation from ACS. The ACS report and accreditation certificate are  
10 expected in three weeks.

11           SFMC continues to provide trauma services and is certified by Los Angeles City Emergency  
12 Medical Services and serves as a designated trauma center.

13           **c. Leapfrog Data and Ratings**

14           SFMC Compass Data has not been updated during this PCO reporting cycle. However, as  
15 indicated in the PCO's sixth report, SFMC Leapfrog status increased from an F grade to a C grade.  
16 SFMC will continue to put forth initiatives that are expected to further improve the institutions  
17 Leapfrog grade.

18           Unfortunately, considerable amount of capital is needed to obtain high Leapfrog grades and  
19 to maintain the grades over time. For example, Computerized Physician Order Entry (CPOE), Bar  
20 Code medication administration, Surgical Volume, and ICU Physician staffing require financial  
21 support to increase the Leapfrog scores.

22           SFMC administration believes that after the institution of an electronic medical records  
23 system, Leapfrog statistics will continue to rise. The PCO concurs.

1                   **3. Seton Medical Center and Seton Coastside**

2                   **a. Administration Discussions**

3                   The PCO discussed and was updated on several ongoing items by Derek Drake, CNO, and  
4 James Jackson interim CEO, via phone conference.

5                   The PCO and administration discussed several issues that occurred during the reporting  
6 cycle which include a State Board of Pharmacy survey, CDPH skilled nursing facility standard  
7 survey, College of Pathologist Laboratory Survey, and several CDPH self-reported events.

8                   The PCO was also notified that Mark Fratzke, DNP is no longer the Chief Executive Officer  
9 of Seton. James Jackson was appointed as interim CEO. Mr. Jackson was previously Seton  
10 Medical Centers Chief Operating Officer.

11                   The new CT scanner installation and construction plans remain with CAL-OSHA. CAL-  
12 OSHA has yet to approve the construction plans despite the potential impact to patient care and  
13 expense to the hospital system.  
14

15                   The alternative CT scanners, mobile trailer CT scanner housed outside the emergency  
16 department and the CT scanner scheduled for replacement, remain operational and provide  
17 adequate care to the patients.  
18

19                   SMC continues to perform well on several quality metric indicators including computerized  
20 order entry and geometric length of stay.

21                   The Hospitalist contracts were terminated on September 30<sup>th</sup>, 2019. According to  
22 administration, the Hospital Medicine service did not encounter any interruptions in patient care.  
23 Most of the Hospitalist continue to provide services and remain on the medical staff. No other  
24 physician staffing changes were noted during this reporting cycle.  
25  
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1           **b. CDPH**

2           The PCO reviewed all CDPH reports along with plan of correction details. It does not  
3 appear that the incidents were related to the finances associated with the bankruptcy of the Debtors.

4           Two self-reported events occurred during this PCO reporting cycle.

5                       **i. Fall Event**

6           The first involved a fall incident that resulted in patient injury. The patient sustained a hip  
7 fracture requiring surgical intervention to repair.

8           The circumstances surrounding the incident were reviewed by the PCO and appeared to  
9 unavoidable. According to the records reviewed, the patient spent most of the day with her  
10 daughter outside the facility attending an eye appointment that required pupil dilatation, which can  
11 cause visual acuity and depth perception deficits.

12           Upon return to the facility, the patient wandered from immediate site of the staff. While the  
13 charge RN was assisting the patient back to a common area, the patient sustained a fall, injuring her  
14 right hip.

15           The patient was taken to the emergency department and diagnosed with a right hip fracture  
16 that required a hemiarthroplasty.

17           Despite being a common occurrence in skilled nursing facilities, administration chose to  
18 perform a Root Cause Analysis (RCA) to determine if the incident was avoidable. The results of  
19 the RCA did not lead to any personnel, environmental or building structure changes. The RCA also  
20 highlighted the facility complied with staffing ratios at the time of the event.

21                       **ii. Fire Risk**

22           The second incident was related to a potential fire risk at the facility. According to the  
23 records reviewed by the PCO, an employee found a metal urn, outside the facility that was putting  
24 out white smoke. The employee immediately gained access to the metal urn and found that a  
25  
26  
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1 cigarette butt was burning a napkin, and put it out. The employee immediately contained the  
2 situation. However, and at issue, the employee failed to report the incident to administration  
3 immediately after the event.

4 The facility performed mandatory and extensive education, fire safety training seminars, fire  
5 and a facility wide smoking policy in-service.

6 The PCO received, via the OneDrive, 20 documents that outline the details of the  
7 investigation, employee educational packets, photographs of the incident, and a complete corrective  
8 action plan.

9  
10 The PCO is satisfied that the facility corrected the issue and patients are not at risk of harm.

11 **c. Lawsuits**

12 The PCO did not find any new lawsuits or professional liability reports filed.

13 **d. CMS Findings**

14 Reflected in the last PCO report, CMS has cleared the “*Immediate Jeopardy*” and is no  
15 longer under heightened CMS surveillance.

16  
17 **e. Leapfrog Data**

18 SMC leapfrog grade increased to a B rating. Contributing to the increase in the Leapfrog  
19 grade is the close relationship with the Hospitalist team and their willingness to adhere to the CMO  
20 demands for CPOE compliance, among other factors.

21 SMC has the highest leapfrog rating in the healthcare system. Administration continues to  
22 accent and reinforce positive performance that led to the B rating.

23 **f. Skilled Nursing Standard Survey**

24 The PCO and administration reviewed and discussed each item of the CDPH Skilled  
25 Nursing Facility (SNF) standard survey results.  
26  
27  
28

1 On September 13, 2019, CDPH licensing and certification program conducted a standard  
2 survey of the SNF at Seton Medical Center and Seton Coastside to determine the facilities  
3 compliance with federal conditions of participation (COP) requirements.

4 The survey found multiple deficiencies that were classified as widespread but constitute no  
5 actual harm but have potential for more than minimal harm as defined in Title 42, *Code of Federal*  
6 *Regulations* (CFR).

7 The highest scope and severity found for any of the deficiencies listed by CDPH were  
8 classified as an "F". An "F" classification is defined by the Scope and Severity, **NOT** "Substandard  
9 Quality of Care" yet has the potential to cause minimal harm.

10 The PCO discussed the deficiencies that the PCO felt could impact patient care to the extent  
11 of causing harm.

12 SMC submitted the plan of care responses to CDPH and are awaiting the revisit validation  
13 survey, with the date to be determined by CDPH.

14 Below are the deficiencies observed by the surveyors during their visit performed on  
15 September 10<sup>th</sup>, 2019, through September 13<sup>th</sup>, 2019.

16 **List of Deficiencies Table**

<b>(X4) ID Prefix Tag Deficiencies</b>	<b>Summary of Deficiencies</b>
19 F 558 §483.10(e)(3) 20 Reasonable accommodations 21 needs/preferences: 22 23	During the observation from the surveyor a resident was not assisted by the staff with his meals as ordered by the physician. In addition, the surveyor noted that a resident request for an electronic scooter or wheelchair was not acted upon as ordered by his physician.
24 F625 §483.15(d)(1)(2) 25 Notice of bed-hold policy before/upon 26 transfer. 27 28	Bed hold means holding or reserving a residence bed while the resident is absent from the facility for therapeutic leave or hospitalization. The surveyor identified that a patient was not notified of the bed hold policy in writing when transferred to the hospital.

1	F656 §483.21(b)(1)	Multiple deficiencies were noted in this
2	Development and implementation of a	section that have been addressed by the
3	comprehensive care plan.	facility and a plan of correction submitted to
4	F658 §483.21(b)(3)(l)	CDPH.
5	Services provided by professional standards.	Surveyor observed that medication was not
6		administered as ordered; oxygen was not
7	F689 §483.25(d)(1)	delivered as ordered.
8	Free of accident	The surveyor noted that an exit door was
9	hazards/supervision/devices.	held open by a front wheel walker for
10		convenience of the staff placing patients at
11	F692 §483.25(g)(1)-(3)	risk for injury and harm.
12	Nutrition/hydration status maintenance.	Dietary orders were not followed per the
13		physician's orders.
14	F700 §483.25(n)(1)-(4)	Surveyor found multiple deficiencies over
15	Bed rails and restraint devices.	multiple patients during the survey.
16		
17	F755 §483.45(a)(b)(1)-(3)	Surveyor observed a controlled substance
18	Pharmacy Services, Procedures, Pharmacist	scheduled to was removed from a locked
19	and Records.	device before the pharmacist was able to
20		verify the medication for administration.
21		This occurred on several occasions during
22		the survey.
23	F761 §483.35(g)(h)(1)(2)	Based on the observation of the surveyor, the
24	Labeling and storage of drugs and	facility failed to store drugs and biologicals
25	biologicals.	in a manner that prevented access by
26		unauthorized personnel went to of four
27		medication carts were unlocked during the
28		survey.
	F804 §483.60(d)(1)(2)	The surveyor observed multiple deficiencies
	Nutritive value and appearance of meals.	in stored food temperatures for a palatable
		and attractive safe and appetizing
		temperature.
	F842 §483.20(f)(5), §483.70(i)(1)-(5)	The surveyor found deficiencies in the
	Resident records with identifiable	comprehensive care plan regarding sufficient
	information.	information to identify the resident, provide
		justification before administering
		antipsychotics or sedatives as a clinical
		restraint for behavior

1 2 3 4 5	F849 §483.70(o)(1)-(4)  Hospice services.	Surveyor observed failure to ensure coordination of hospice care and services were provided for three or four residents. In addition, inadequate references were available to ensure immediate contact with the members of the interdisciplinary group that provides the management of the hospice patients. The surveyor noted multiple deficiencies in this area.
6 7 8 9	F867 §483.75(g)(2)(ii)  Quality assurance performance improvement /quality assessment and assurance improvement activities.	Based on the interview and surveyor observations the facility did not implement its quality assessment and assurance plan to identify systemic deficiencies and to develop action plans to address them.
10 11 12 13 14	F880 §483.80(a)(1)(2)(4)(e)(f)  Infection prevention and control.	The surveyor observed a staff member disposing of urinary bag cover and toilet paper soaked with blood-tinged colored urine in a regular garbage container, and uncovered, unlabeled, oxygen cannula tubing was left hanging on the oxygen cylinder, and a suction canister with cloudy liquid was found without a start date.

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The PCO carefully reviewed the CDPH standard survey seventy-seven page deficiency document and SMC’s subsequent Plan of Correction (POC) responses, which the PCO believes to be adequate.

**g. Board of Pharmacy Survey**

The Board of Pharmacy performed a survey on October 15, 2019. The survey found numerous deficiencies in the area of sterile medication compounding.

A detailed report of deficiencies and plan of correction was submitted to the PCO for review. The PCO is satisfied that the pharmacy director has performed and implemented a robust corrective action plan. The plan of correction has been accepted by the Board of Pharmacy with an expected verification survey by the Board of Pharmacy soon.

1 The PCO will continue to closely monitor any further events regarding the pharmacy as this  
2 is the second Board of Pharmacy survey that identified deficiencies in sterile compounding at SMC.

3 The first survey that identified sterile compounding deficiencies resulted in the resignation  
4 of the pharmacy director.

5 The plan of correction submitted to the Board of Pharmacy by the pharmacy director  
6 outlined an extensive and robust educational plan that outlines frequent and extensive pharmacist  
7 training in the area of sterile compounding.  
8

9 **h. College of American Pathologist Survey**

10 The survey was completed, and plan of corrections are in progress.

11 **3. St. Vincent's Dialysis Center**

12 The unit is incorporated in St. Vincent's Hospital and continues to function normally. No  
13 reported or identified adverse events were discovered during this reporting cycle.

14 Administration continues to perform real-time monitoring rounds to ensure compliance with  
15 the corrective action plans implemented close to a year ago.  
16

17 **4. TAIL COVERAGE**

18 Medical malpractice tail coverage is an addition or an endorsement to an existing  
19 professional liability policy that allows coverage in claims-made policies. Patients who have  
20 potentially suffered harm often do not discover the malpractice for some time into the future. These  
21 potential plaintiffs are yet to be identified. Given the nature of hospital care in general, and this  
22 system's claims history in particular, the chance that there will be no suits is near zero. The buyer is  
23 not assuming liability for past patients.  
24

25 These patients of the debtor are very often poor and have limited recourse. Without a  
26 professional liability policy to fall back upon, future medical and non medical needs (as a result of  
27 malpractice) may end up unaddressed.  
28

1 The PCO had a conference with Mr. Adcock (CEO), Ms. Elspeth Paul (General counsel),  
2 and Dr. Del Junco (CMO) just prior to the court hearing of October 14, 2019, in a conference room  
3 at the courthouse. The PCO was assured that tail coverage would be forthcoming.

4 Since that time, the PCO has yet to receive evidence of the tail coverage that was requested.

5 Corporate general counsel reports that there will be tail coverage for the physicians who  
6 were employees of the debtor, but has not reported or kept to the agreement relative to hospital tail  
7 coverage.  
8

## 9 V. CONCLUSIONS

10 The issues that deserve attention are:

- 11 1. The effect that the Debtors' finances have and will have in relation to the recent CMS  
12 survey deficiencies that require remediation.
- 13 2. The consequences of the Debtors placing the UNOS certified Liver Transplant program on  
14 suspension.
- 15 3. The need for malpractice tail coverage insurance for the hospital.  
16

### 17 1. SETON, SETON COASTSIDE AND CDPH

18 The issues raised by CDPH are being thoughtfully corrected.

### 19 2. LIVER TRANSPLANT PATIENTS

20 Despite best efforts by the leadership of SVMC, the requirements of UNOS remain unmet.  
21 The liver transplant patients have not been successfully assigned and accepted, in writing, by a  
22 certified program, as required by UNOS/OPTN strict regulations. These patients need ongoing care  
23 that will not be in place by the contemplated sale closing later this month.  
24

25 **The buyer has not agreed to take on these patients.**

26 Someone or some entity must assume and pay for this care. The Debtors will be gone.  
27 Moreover, it is not the buyer's responsibility.  
28

1 The PCO statute was written for exactly this situation based on the outrage of Congress  
2 when nursing home patients were put out to the parking lot! We cannot let this happen again.

3 The Debtors signed a contract with UNOS, and the patients (third party beneficiaries) have  
4 detrimentally relied by seeking care from the Debtors. The patients are entitled to the benefit of  
5 their bargain, and their very lives are at stake.

6 Someone or some entity (including the buyer if willing) should be compensated for  
7 assuming care and then caring for this very vulnerable group of patients. The court, or the Debtors  
8 with court approval, should fashion a remedy for these patients.

9 SVMC began the difficult certification process with UNOS, the transplant certifying  
10 agency, long before the Debtors filed. Transplant services are the most rigorously monitored  
11 programs in health care.

12 SVMC hired a transplant surgeon, a board-certified transplant anesthesiologist, a  
13 hepatologist, along with a large number of support personnel. A special clinic was set up.

14 It is well known that the liver transplant patients are the most critically ill of all patient  
15 subtypes, both pre and post operatively. Post-operative liver transplant patients require weekly  
16 close follow upon hospital discharge. The patients are initially seen weekly and then every two  
17 weeks. Their medication adjustment is aided by a dedicated transplant pharmacist. Any interruption  
18 of this process, albeit small, can result in rejection of the organ and death.

19 SVMC began its liver transplant program prior to filing for bankruptcy protection but did  
20 not do its first transplant until months after filing. The addition of a functioning second transplant  
21 service, with kidney-pancreas already in place, would create a "Center of Excellence". This Center  
22 of Excellence status would improve reimbursement to the hospital and allow private insurance  
23 carriers to contract with the hospital.  
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1 The Liver Transplant Program was viewed as an asset and thus was allowed to thrive,  
2 despite losing money initially. Note that by CMS rules, the first ten transplants are not reimbursed  
3 until the program's results have been validated.

4 It was not until three months ago that either the Debtors or the buyer would verify that they  
5 would continue the Liver Transplant Program. The buyer viewed the loss associated as being too  
6 great for the hospital to remain viable. This asset became a liability. The Debtors suspended the  
7 liver transplant program with UNOS and terminated, effective November 2019, the physician  
8 employees and the liver transplant staff via Verity Medical Group (not a Debtors, but funded by the  
9 Debtor).

10  
11 The Attorney General did not impose maintenance of the liver transplant program as a  
12 condition to approving the sale but did note that the patients should be transferred to other liver  
13 transplant programs. In practice this is very difficult to accomplish. The Debtors' emergency  
14 motion verified that they will not and cannot continue the liver transplant program as they cannot  
15 close the sale with any of the imposed conditions. During this reporting cycle, the Attorney General  
16 the Debtor and the Buyer came to an agreement regarding sale conditions.

17  
18 SVMC currently participates in a UNOS/OPTN authorized kidney and pancreas program  
19 that will continue to operate after the sale of the hospital according to Dr. Del Junco. Failure to  
20 follow the regulations set forth by OPTN/UNOS with respect to the Liver Transplant Program,  
21 could jeopardize the UNOS/OPTN status of the kidney and pancreas transplant program.

### 22 **3. TAIL COVERAGE**

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24 Thus far, the Debtors have not provided for tail coverage for the hospitals. The lack of tail  
25 coverage will certainly result in harm to patients as a direct consequence of the Debtors' finances

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Since the buyer is not assuming this responsibility, it is the belief of the PCO, that the Debtor should be required to provide tail coverage for the hospital in order to protect the health and safety of the patients

To remain within the boundaries of Bankruptcy Code Section 333, not a single patient should be sacrificed for the benefit of the estate.

Dated this 3<sup>rd</sup> day of December, 2019.

  
\_\_\_\_\_  
Jacob Nathan Rubin, MD, FACC, Patient Care  
Ombudsman

**Exhibit 1**

Last Name	First Name	Last MELD	Patient Preference	Insurance	Status	Status Date	Accepting Center	Transfer Date	Chart Sent?	Scheduled Appt	Action Items
Transplanted											
			Redirect UCLA	Medicare/Tricare	10/30: Patient still reviewing information provided, will call Anna with top choice. 10/31 requested call to patient from UCLA post clinic. 11/5 placed referral, sent records and confirmed with patient. Katherine Meneses NP primary contact, she will follow until new Santa Monica Hepatology clinic is set up. Appt promised within 1 month or sooner if needed. 11/21/19: UCLA contacted patient, appt in early December.	11/21/2019	UCLA		Yes		N/A
			Redirect - USC	Medi-Cal	Keck USC Status Update: Pt financially clear, assigned to clinical coordinator, pending appt scheduling	11/21/2019	USC		Yes		Pending appt at USC, seeing Naraghi at St. Vincent.
			Redirect - Scripps La Jolla or UCSD	Blue Cross PPO	Pt seen at Scripps 10/21/19, UNET forms transferred 11/5/19, CAGH accepted	10/23/2019	Scripps	11/5/2019	Yes	10/21/2019	No further action necessary
			Keck	Medicare/LA Care	Keck USC Status Update: Pt financially clear, pending pt completion of health questionnaire	11/21/2019	USC		Yes		Pending patient filling out health questionnaire
			Dr. A El Segundo	Medicare/Aetna	Pt preference to stay with Dr. A, El Segundo clinic, confirmed 10/30/2019	10/30/2019	N/A	N/A	Yes	N/A	N/A
			Redirect UCLA	Medi-Cal	Pt preference UCLA, but also scheduled with Dr. A at El Segundo, VM to UCLA post coordinator 10/30/19 Referral placed to UCLA post clinic - contact Katherine Meneses 11/6/19 Seen by MD Felim at LLUMC, UNET forms transferred 11/5/2019, CALL accepted	11/21/2019	UCLA		Yes		Awaiting response from Katherine re: appt date
			Loma Linda	MediCal FFS	Keck USC Status Update: Pt financially clear, assigned to clinical coordinator, record review in progress, pending appt scheduling	10/31/2019	LLUMC	11/5/2019	Yes	Seen 10/09/2019 by hepologist	N/A
			Redirect per insurance	Regal	Keck USC Status Update: Financial clearance in progress, not yet cleared	11/21/2019	USC		Yes		Pending appt at USC
			Redirect per insurance	Medicare (Primary)	Keck USC Status Update: Pt financially clear, assigned to clinical coordinator, record review in progress, pending appt scheduling	11/21/2019	USC		Yes		Pending financial clearance
			Redirect based on location	Medi-Cal	Keck USC Status Update: Pt financially clear, assigned to clinical coordinator, record review in progress, pending appt scheduling	11/21/2019	USC		Yes		Pending appt at USC.
			Redirect per insurance	Regal	Keck USC Status Update: Pt financially clear, assigned to clinical coordinator, record review in progress, pending appt scheduling	11/21/2019	USC		Yes		Pending appt at USC.
			Redirect, pending discharge, UCSF	Managed Care	inpatient at Natividad Salinas, appt at Stanford scheduled as outpatient.	11/21/2019	Stanford				Pending update on appt. inpt vs outpatient.
			Redirect - Scripps La Jolla	Blue Shield PPO	Pt preference Scripps, ROI completed, Anna follow up with Lynndee @ Scripps 10/30/19. 11/7/19: forwarded records to USC for possible earlier appt. 11/15/2019 pt admitted and accepted by USC 11/21/19: Follow-up appt 12/6/2019	11/21/2019	USC	11/15/2019	Yes	11/22/2019	Accepted at USC, follow up appt 12/6/19.
Waitlisted											
		16	Redirect per personal Hepatologist	Medicare/Kern County	10/8/2019: Left message to follow up and confirm plan for patient. 11/21/19: appt scheduled at Cedars.	11/21/2019	Cedars				Appt scheduled at Cedars. Med refills handled by SVMC for now.
		7	Redirect USC, UCLA, Loma Linda	BC PPO	Anna emailed info on centers 10/30/19 Follow up call 11/7/19 - patient does not wish to pursue transplant at this time, removed from WL.	11/7/2019	N/A	N/A	N/A	N/A	
		12	Redirect per insurance	BC Regal	Provided information in email to Keck USC, Ryan primary contact, appointment pending. 11/21/19: pending appt 12/2 or 12/9	11/21/2019	USC		Yes		Appt to be scheduled for 12/2 or 12/9
		8	Redirect per insurance	Regal	Keck USC Status Update: Pt seen on 10/09/2019, will be presented at selection committee within the next two weeks	11/21/2019	USC	10/9/2019	Yes	Seen 10/9/2019	Work up complete, pending presentation to selection committee.
		16		Medi-Cal	Redirect to Dr. Mena, recommended removal from waitlist per Dr. Gutierrez, pending recommendation from Mena.	11/15/2019			Yes	11/22/2019	Appt with Mena 11/22/19 with USC hepatologist.
		30	Redirect USC - Transplanted		Redirected USC - Transplanted	10/8/2019	USC	9/25/2019	Yes	Transplanted	Transplanted
		11	Redirect per insurance	Managed Mcal Omnicare	Provided information in email to Keck USC, Ryan primary contact 11/21/19: pending financial clearance, appt will be early/mid December. Keck USC Status Update: Pt seen on 11/04/2019, in active work-up, requires additional 2-3 months prior to psychosocial evaluation/clearance	11/21/2019	USC		Yes		Pending financial clearance and appt scheduling.
		12	Redirect USC	BS PPO		11/21/2019	USC	11/4/2019	Yes	11/24/2019	Actively being worked up, need cardiac and psychosocial clearance.
Referral											
			Can be directed to Cedars, Scripps, UCLA, prefers Cedars Unable to Contact - Tell# out of service. Contacted Referring Dr. Rojter 213-250-3344, redirect in process	BS PPO	Pt to discuss options with Dr. Mena	10/24/2019	N/A	N/A	N/A	N/A	Pending pt decision with referring physician
			Pending call back GI Only with Dr. G, not transplant candidate	Health Net MCAL	USC COE, Pt must get referral from PCP, CASV to follow with PCP	10/2/2019	USC				No further action necessary
			UCLA	Medicare/Medical	Referring physician, taken care of	10/23/2019	n/a	N/A	N/A	N/A	No further action necessary
			Redirect per insurance LA CARE/ Regal	Cigna	Pending financial clearance for UCLA	11/1/2019	N/A	N/A	N/A	N/A	No further action necessary
			Pending call back - Insurance will dictate, not currently followed by SVMC	LA CARE/ Comm Family Care	Keck USC Status Update: Pt scheduled for 12/02/209	11/21/2019	USC				Pt scheduled to be seen 12/02/2019
			Pending call back from Oxnard Manor Home Health	Medicare/ Gold Coast	UCLA, pending clearance, financial coordinator attempted to reach pt with no answer	10/29/2019					Send a letter to patient, Spanish
			USC	Medicare/Kern Family	Keck USC Status Update: pending appt scheduling on 12/02/ or 12/09	11/21/2019	USC		No		Send a letter to patient, English and Spanish
			Unable to Contact - Tell# out of service	BS Promise MCAL Global Care	Unable to contact	10/23/2019					Possible hospice care; pt to be scheduled at Keck either on 12/02 or 12/09
			Redirect per insurance	Regal	Keck USC Status Update: pt scheduled for 12/02/2019	11/21/2019	USC				Pt scheduled to be seen 12/02/2019
			Patient does not answer, message left in Arm	Regal	Keck USC Status Update: pt clinically cleared, pending financial clearance	11/21/2019	USC				Clinically cleared by USC, pending financial clearance
			Contact phone number disconnected On hold for referral per Hepatologist Dr. Perumalsami	Healthcare LA/LA Care	Redirected UCLA, pending copy of approval Per patient, Bill improved, following weekly with Hepatologist, will call if needs assistance	10/29/2019	UCLA				No further action necessary
			Expired		Expired	10/8/2019	n/a	N/A	N/A	N/A	No further action necessary
			Redirect Loma Linda	Medi-Cal	Referral made to Loma Linda	11/1/2019	Loma Linda	N/A	N/A	N/A	Ask Anna for last status, no further action necessary
			Redirect per insurance Redirected to UCSD	Regal Medi-Cal	Regal Processing Redirect, currently inpt at Mission Community for GI bleed, approved for USC Redirected to UCSD	10/24/2019 9/27/2019	USC UCSD	N/A	N/A	N/A	No further action necessary Ask Anna for last status

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			Expired	Medicare/Medical	Expired	9/27/2019						
			Call back with interpreter 9/30/19	LA CARE/Healthcare LA IPA	Redirected to UCLA	10/8/2019	UCLA					Ask Anna for last status
			Redirect per insurance		insurance denied referral, redirected by insurance	9/25/2019	N/A	N/A	N/A	N/A		No further action necessary
			Expired		Expired	9/25/2019						
			Expired		Expired	9/25/2019						
			Under care of Oncologist, previously denied for transplant by USC, does not wish to be referred at this time.	Medicare/LA CARE	Under oncologic care, does not wish to be referred for transplant at this time.	9/27/2019	N/A	N/A	N/A	N/A		No further action necessary
			Redirect per insurance	Regal	Keck USC Status Update: pending appt scheduling	11/21/2019	USC					Pending appt scheduling with Keck
			Redirect per insurance	Regal	10/23/2019 Provided information in email to Keck USC, Ryan primary contact 11/13/2019 - denied for listing at USC.	11/13/2019	USC		11/13/2019	Yes	Appt completed, not a candidate for transplant.	No further action needed, USC to send denial letter.
			Redirect per insurance	Regal	Regal Processing Redirect, pt being re-referred by Dr. Mena	10/23/2019	N/A	N/A	N/A	N/A		No further action necessary
			Redirect per insurance	Regal	Regal Processing Redirect, Aracell to submit request for Cedars, send back to Mena, pending approval	10/29/2019	Cedars					Approved for Cedars, pt seen by Mena last week. No further action necessary. Include in Mena email
			Per patient, does not wish to pursue transplant at this time pending eviction from home and unemployment. Gave direct cell phone number for assistance as needed.	unknown	Declines new referral at this time	9/27/2019	N/A	N/A	N/A	N/A		No further action necessary
			Redirect per insurance	Medicare/Inland Empire	Medicare/Inland Empire Processing Redirect	11/1/2019	N/A	N/A	N/A	N/A		Ask Anna for last status; no further action necessary
			Redirect per insurance	UHC PPD	Cedars seen 10/25 by Hepatologist	10/29/2019	Cedars seen 10/25		10/25/2019	N/A	Seen at Cedars	No further action necessary, Cedars will request medical records as necessary
			Redirect per insurance	Medi-Cal	Moved to OC, needs help finding closest txp center. 11/5/19 Confirmed appointment for Loma Linda 11/25/19	11/5/2019	LLUMC			Yes	11/25/2019	Pt's daughter emailed back with questions about LLUMC. Director responded, pending reply. 11/5, appointment confirmed, connected daughter Danielle to office and cell phone of Erin Wells, clinical manager LLUMC.
			Redirect per JG	BC EPO	Per Dr. G, interested in UCLA, Dr. Saab hepatologist to make formal referral to UCLA	11/1/2019	UCLA	N/A	N/A	N/A		Per pt and pt's father, Dr. Saab hepatologist to make formal referral to UCLA, no further action necessary.
			Redirect per insurance	Regal	Keck USC Status Update: Seen by USC oncologist 10/07, pending tumor removal, forwarded to hepatology	11/21/2019	USC					No further action necessary
			Redirect per insurance	Regal	Keck USC Status Update: pending clinical clearance	11/21/2019	USC				Per pt scheduled appointment, unknown date	Pending clinical clearance
			Expired		Expired	9/25/2019						
			Redirect per insurance	Regal	Keck USC Status Update: seen by USC at Mena's office on 11/21/2019	11/21/2019	USC					No further action necessary

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**Exhibit 2**



# *Bylaws*

**Effective Date: May 14, 2019**

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## **Article I: Membership**

There are seven categories of members in the Organ Procurement and Transplantation Network (OPTN):

1. Transplant hospital members
2. Organ procurement organization (OPO) members
3. Histocompatibility laboratory members
4. Medical/scientific members
5. Public organization members
6. Business members
7. Individual members

References in these Bylaws to members include all seven membership categories, unless otherwise noted.

### **1.1 Membership Requirements**

This section provides an overview of membership in the OPTN. The requirements for applying to be an OPTN member are defined in *Appendix A: Membership Application and Review* of these Bylaws, including:

- The application process for membership.
- The process for appealing denials of membership.
- The election process.

#### **A. Membership Responsibilities**

OPTN members will:

1. Review the OPTN Final Rule, Charter, Bylaws and Policy.
2. Comply with all obligations of membership.
3. Promptly review materials distributed during the public comment period as part of the OPTN policy development process.
4. Promptly review policy notices distributed as part of the OPTN policy development process.
5. Assign representatives to vote on affairs of the OPTN, if they are voting members.

#### **B. Overview of the Voting Process**

This section provides an overview of the voting process for OPTN members. Only these six membership categories have voting privileges:

1. Transplant hospital members
2. OPO members
3. Histocompatibility laboratory members
4. Medical/scientific members
5. Public organization members
6. Individual members

Business members do not have voting privileges in the OPTN.

OPTN members designated Members Not in Good Standing do not have voting or other membership privileges. However, members designated Members Not in Good Standing must continue to fulfill their OPTN member responsibilities.

The table below summarizes the voting privileges for each OPTN membership type:

<b>Membership Type</b>	<b>Number of Votes</b>	<b>Additional Requirements to Qualify for Voting Privileges</b>
Transplant hospital	One per transplant hospital	The transplant hospital must have current approval as a designated transplant program for at least one organ.
OPO	One per OPO	The OPO must be independent, or a hospital-based OPO that is able to demonstrate all of the qualifications according to <i>Section 1.3.C</i>
Histocompatibility laboratory	One per histocompatibility laboratory	The histocompatibility laboratory must be independent, according to <i>Section 1.4.</i>
Medical/scientific	One per Medical/scientific member	None
Public organization	No more than 12, cast by public organization member electors	Public organization members must provide services or be involved in national or regional activities.
Individual	No more than 12, cast by individual member electors	None

A majority of all members eligible to vote, either in person or by proxy, constitutes a quorum for transacting business at any meeting of members. When a quorum is achieved, majority vote of members may transact any business at the meeting, except when different voting requirements are defined in these Bylaws. A member or member elector may only vote once on each resolution.

**C. Meetings**

Members have an annual meeting to elect a Board of Directors and officers, and to address other OPTN matters. The annual meeting of members may be held in conjunction with a Board of Directors meeting.

A member or member elector who signs a waiver of notice will be exempt from the requirement of written notice. A member or member elector who attends a meeting is assumed to have received timely and proper notice of the meeting unless the member or member elector attends only to object that the meeting is not lawfully convened. A notice sent to a member or member elector who is not eligible to vote does not imply that the member or member elector may vote.

The OPTN will not pay or reimburse a member’s cost to attend meetings of OPTN members.

### **Special Meetings**

Special meetings of the members may be called at any time by the president, Executive Director, a majority of the Board of Directors, or by written request of a majority of voting members and member electors. Notice of a special meeting must state the time, place, and purpose of the meeting and be provided to each member not more than 60 days or fewer than 25 days before the proposed date of the meeting.

### **Closed Sessions of Meetings**

Meetings of the OPTN membership are usually open to the public. However, closed sessions may be held for discussions involving confidential matters which may include OPTN membership approval, credentials, monitoring, or disciplinary matters as defined in the OPTN contract. Matters involving individuals where an open meeting would clearly compromise their privacy will also be reviewed in closed sessions. Representatives from the Federal Government serving on the Board of Directors, or their chosen representatives, are not excluded from closed sessions of OPTN meetings.

## **D. Expenses**

If the OPTN Contractor incurs any expenses on behalf of a member by providing organ transplantation assistance to the member, the member must reimburse the OPTN Contractor in full. Examples of expenses include, but are not limited to:

- Courier transport of an organ.
- Commercial airline or private aircraft for transporting an organ.
- Repackaging of organs or tissue.

Transplant hospital, OPO, or histocompatibility laboratory members must pay all OPTN fees, charges, or other financial obligation within 30 days to the OPTN Contractor or be considered in violation of OPTN membership requirements.

## **E. Member Compliance**

By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations, which include *all* of the following:

1. Applicable provisions of the:
  - a. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*
  - b. OPTN Final Rule, 42 CFR Part 121
  - c. OPTN Bylaws
  - d. OPTN Policies
2. Acting to avoid risks to patient health or public safety
3. Fulfilling all requests for information

## **F. Member Reviews and Evaluations**

The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital, histocompatibility, and OPO member for compliance with OPTN Obligations. All compliance monitoring is performed using guidelines developed by the OPTN Contractor.

## **G. Reporting Potential Noncompliance with OPTN Obligations**

Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself.

All incidences of potential noncompliance are referred for further review as outlined in these Bylaws. Any member who fails to comply with OPTN Obligations may be subject to actions as set forth in these Bylaws.

## **H. Affiliated Organizations**

The OPTN Bylaws do not in any way require an OPTN member to:

1. Become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN.
2. Comply with bylaws of any parent, sponsor, contractor, or affiliated organization of the OPTN.
3. Assume any corporate duties or obligations of any parent, sponsor, contractor, or affiliated organization of the OPTN.

## **I. Removal of Members**

Transplant hospital members who no longer qualify as an OPTN member will be reviewed according to *Appendix L: Reviews and Actions*.

All other OPTN members who no longer qualify for OPTN membership may be removed as members through any of the following procedures:

- The member itself may request to voluntarily withdraw from OPTN membership by forwarding a written request to the Executive Director.
- The OPTN may notify the member in writing that, unless the member demonstrates within 60 days of notification that it continues to meet applicable membership criteria, the member's OPTN membership will be terminated, even if the member does not request removal.

If, within 60 days of notification, the member demonstrates, to the satisfaction of the OPTN, that the member meets OPTN membership requirements, the OPTN will withdraw its notice of termination.

If the member fails to demonstrate that it continues to meet OPTN membership requirements, its membership in the OPTN will terminate on the 60th day after notification of termination by the OPTN. The member can appeal this decision to the Secretary of the U.S. Department of Health and Human Services (HHS). In the event a member exercises this right of appeal, the member will notify the OPTN Contractor of this by any method that can be tracked and provides proof of receipt, such as:

- Commercial overnight delivery service
- Secure electronic communication
- Registered or certified mail, return receipt requested

Pending a decision on the appeal, the removal process will continue unless the Secretary of HHS directs otherwise. If the appeal is denied, the process will be continued or reinitiated, as

applicable. Any other decision by the Secretary of HHS will be submitted to the Membership and Professional Standards Committee (MPSC) or Board of Directors to act on the Secretary's decision.

Any member removed from OPTN membership for any reason may later reapply for membership.

The Board of Directors will periodically review these requirements and update these Bylaws with additional membership requirements for members. Failure to fulfill such requirements will be cause for any corrective action described in *Appendix L: Reviews and Actions*.

## **1.2 Transplant Hospital Members**

A transplant hospital member is any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.

### **A. Transplant Hospital Member Representatives**

Transplant hospital members must:

1. Appoint a representative to vote and act for the member on all OPTN business.
2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

### **B. Transplant Hospital Membership Terms**

Transplant hospital members have unlimited terms.

### **C. Transplant Hospital Membership Voting Privileges**

Each transplant hospital member has one vote, providing that the transplant hospital has *both* of the following:

1. Final approval of its membership by the OPTN Board of Directors.
2. Current approval as a designated transplant program for at least one organ.

### **D. Registration Fees**

Transplant hospital members are responsible for the payment of an OPTN Registration Fee for each transplant candidate registered by that member on the waiting list database maintained by the OPTN Contractor. The OPTN Registration Fee is proposed by the Board of Directors and determined by the Secretary of HHS.

An additional registration fee will be due for a transplant candidate if:

- A candidate is given an inactive status or removed from the waiting list without receiving a transplant and is not placed back on the list within the 90-day grace period.
- A recipient has received a transplant but is put back on the waiting list for another transplant. However, no additional registration fee will be due for an islet candidate who is removed and,

if the option to re-register is offered during the removal process, immediately re-registered for an islet infusion.

- A candidate is transferred to a transplant hospital *outside* the original OPO Donation Service Area. A new registration fee must be paid by the receiving hospital.
- The potential recipient is listed at multiple transplant hospitals. A registration fee must be paid by each transplant hospital that places the candidate on the waiting list.

Members who register candidates needing more than one organ (for example, kidney and pancreas) are only charged one registration fee.

## **E. Removal of Transplant Hospital Members**

Transplant hospital members who no longer meet the qualifications as an OPTN member will be reviewed according to *Appendix L: Reviews and Actions*.

## **1.3 OPO Members**

An OPO member is any organ procurement organization (OPO), certified by the Center for Medicare/Medicaid Services (CMS), and designated as a qualified OPO by the Secretary of HHS.

### **A. OPO Member Representatives**

Voting OPO members have the following responsibilities:

1. Appoint a representative to vote and act for the member in all affairs of the OPTN.
2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

### **B. OPO Membership Terms**

OPO members have unlimited terms.

### **C. OPO Membership Voting Privileges**

Each independent OPO member has one vote.

Hospital-based OPOs may request and will receive separate voting privileges from the supporting transplant hospital only if they can demonstrate *both* of the following:

1. The hospital-based OPO administrative director is not in a leadership role within the transplant programs at the supporting transplant hospital. A leadership role is defined as a role that involves any administrative or organizational decision making responsibilities in any of the transplant programs at the transplant hospital.
2. The hospital-based OPO administrative director is not subordinate to the leadership in any transplant programs at the supporting transplant hospital.

A hospital-based OPO must submit a written request to the OPTN Contractor and provide documentation demonstrating that it meets these qualifications to receive voting privileges.

If a hospital-based OPO that has been granted separate voting privileges no longer meets the qualifications above, then it must notify the OPTN Contractor in writing within 30 days of no longer meeting the qualifications and provide documentation of the reasons the qualifications are no longer met and the OPO will no longer have voting privileges. The OPO may reapply for voting privileges at any time that it meets the qualifications.

#### **1.4 Histocompatibility Laboratory Members**

A histocompatibility laboratory member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, HLA typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO.

##### **A. Histocompatibility Laboratory Member Representatives**

Independent histocompatibility laboratory members have the following responsibilities:

1. Appoint a representative to vote and act for the member on all OPTN business.
2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

##### **B. Histocompatibility Laboratory Membership Terms**

Histocompatibility laboratory members have unlimited terms.

##### **C. Histocompatibility Laboratory Membership Voting Privileges**

Each histocompatibility laboratory member has one vote provided that the histocompatibility laboratory is independent. An independent histocompatibility laboratory is defined as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

#### **1.5 Medical/Scientific Members**

A medical/scientific member is a non-profit organization whose members include medical or scientific professionals with an interest in organ donation or transplantation and that has *either* of the following:

1. Been in operation for at least one year.
2. Letters of recommendation from at least three OPTN transplant hospital, OPO, histocompatibility laboratory, public organization, or medical/scientific Members.

##### **A. Medical/Scientific Member Representatives**

Medical/scientific members have the following responsibilities:

1. Appoint a representative to vote and act for the member on all OPTN business.
2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

## **B. Medical/Scientific Membership Terms**

Medical/scientific members have terms of two years and may reapply for unlimited consecutive terms. Medical/scientific members may resign at any time by written notice to the Executive Director.

## **C. Medical/Scientific Membership Voting Privileges**

Medical/scientific members have one vote on OPTN business.

## **1.6 Public Organization Members**

A public organization member is an organization with an interest in organ donation or transplantation and must have been in operation for at least one year. A public organization member must also be *one* of the following:

1. A hospital that refers at least one potential organ or tissue donor per year.
2. A non-profit organization that engages in organ donation activities, or represents or directly provides support and services to transplant candidates, recipients or their families.
3. A non-profit organization that has letters of recommendation from at least three OPTN transplant hospital, OPO, histocompatibility laboratory, public organization, or medical/scientific members.

## **A. Public Organization Member Representatives**

Public organization members have the following responsibilities:

1. Appoint a representative to vote and act for the member on all OPTN business.
2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

## **B. Public Organization Membership Terms**

Public organization members have terms of two years and may reapply for unlimited consecutive terms. Public organization members may resign at any time by written notice to the Executive Director.

## **C. Public Organization Membership Voting Privileges**

Public organization members have voting privileges through member electors. Public organization members must provide services to OPTN members or be involved in regional or national activities of the OPTN to participate in the election of public organization member electors.

### **The Member Elector Process**

Public organization members choose 12 member electors to represent them. Each member elector is entitled to one vote on OPTN affairs. Eleven of the member electors are regional representatives, who are elected to represent each of the 11 OPTN regions. (See *Article IX: Regions* for more information about the OPTN regions.) The twelfth

member elector is a national member elector, and is elected from the national membership of public organization members.

The member elector process for public organization members follows these guidelines:

1. If there are no members residing within a region then that region will not have a regional member elector. To maintain the twelve member electors, the number of national member electors will increase by one for each region without representation.
2. Any person serving as the named OPTN representative for a public organization member may be nominated to serve as a public organization member elector. Public organization member representatives may submit their own names as candidates for member elector, at the regional or national level.
3. The term of a member elector is two years unless the remaining OPTN membership term of the public organization member with whom the member elector is affiliated is shorter. Member electors may serve consecutive terms.
4. Nominations and elections for member electors will be conducted through the internet using the OPTN website or the United States mail.
5. The Board of Directors will evaluate the number of public organization member electors periodically and adjust the number of public organization member electors so that they make up between approximately three to five percent of the current number of transplant hospital, OPO, and histocompatibility members.

If the total number of public organization members is equal to or fewer than the number of public organization member electors positions available when a vote of the OPTN membership is required, the election process described above will be suspended and each public organization member will have one vote.

## **1.7 Business Members**

A business member must be an organization in operation for at least one year that engages in commercial activities with two or more active OPTN transplant hospital, OPO, or histocompatibility laboratory members.

### **A. Business Member Representatives**

Business members must indicate membership acceptance by designating in writing to the Executive Director the name of a representative and address to which notices may be sent.

### **B. Business Membership Terms**

Business members have terms of two years and may reapply for unlimited consecutive terms. Business members may resign at any time by written notice to the Executive Director.

### **C. Business Membership Voting Privileges**

Business members do not have voting privileges in the OPTN.

## 1.8 Individual Members

An individual member must be a person who meets any of the following criteria:

1. Has served or is presently serving on the OPTN Board of Directors or an OPTN committee.
2. Is a transplant candidate, recipient, or organ or tissue donor.
3. Is the family member of a transplant candidate, recipient, or organ or tissue donor.
4. Is presently employed by or is an independent contractor to OPO, transplant hospital, or histocompatibility laboratory members.
5. Is formerly employed by or is formerly an independent contractor for OPO, transplant hospital, or histocompatibility laboratory members.
6. Is formerly employed by a Federal or State government agency involved in organ donation or transplantation, and who demonstrates continued interest and involvement in organ donation or transplantation.
7. Has an active interest and involvement in organ donation or transplantation demonstrated by at least three letters of recommendation for membership from three other OPTN individual members.

### A. Individual Member Representatives

Individual members must submit in writing to the Executive Director his or her name and the address to which notices are to be sent.

### B. Individual Membership Terms

Individual members have terms of two years and may reapply for unlimited consecutive terms. Individual members may resign at any time by written notice to the Executive Director.

### C. Individual Membership Voting Privileges

Individual members have voting privileges through member electors. The member elector process enables the individual members to be represented by 12 electors.

#### The Member Elector Process

Individual members choose 12 member electors to represent them. Eleven of the member electors are regional representatives, who are elected to represent each of the 11 OPTN regions. (See *Article IX: Regions* for more information about the OPTN regions.) The twelfth member elector is a national member elector, and is elected by all individual members nationally.

The member elector process for individual members follows these guidelines:

1. If there are no members residing within a region then that region will not have a regional member elector. To maintain the twelve member electors, the number of national member electors will increase by one for each region without representation.
2. Any individual member may be nominated to serve as an individual member elector. Individual members may submit their own names as candidates for regional or national member elector.
3. The term of an individual member elector is two years or the remaining OPTN membership term of the individual member, whichever is shorter. Member electors may serve consecutive terms.

4. Nominations and elections for member electors will be conducted through the internet using the OPTN website or the United States mail.
5. The Board of Directors will evaluate the number of individual member electors periodically and adjust the number of individual member electors so that they make up between approximately three to five percent of the current number of transplant hospital, OPO, and histocompatibility members.

If the total number of individual members is equal to or fewer than the number of individual member electors positions available when a vote of the OPTN membership is required, the election process described above will be suspended and each member will have one vote.

## **Article II: Board of Directors**

### **2.1 Composition**

The Board of Directors must have at least 34 but not more than 42 voting Directors.

The following serve *ex-officio* and do not have a vote on the Board of Directors:

- The Executive Director
- The U.S. Department of Health and Human Services (HHS) Project Officer for the OPTN Contract and the Director of the Division of Transplantation, or representatives they designate

All voting Directors serve on the Board without compensation.

#### **A. Officers**

The OPTN Board of Directors includes the following officers:

1. President
2. Vice president
3. Vice president of patient and donor affairs
4. Treasurer
5. Secretary

Additional officers may include one or more assistant treasurers and assistant secretaries, who are periodically nominated by the president and elected by the Board of Directors.

Officers may only hold one position on the Board at a time, except when an officer is appointed by the Board in an additional officer role to fill a vacancy for the unexpired term of another officer.

Officers must perform their duties according to *Article VI: Officers*.

#### **B. Regional Councillors**

The Board must include regional councillors who are representatives chosen by the voting members and member electors of each of the 11 geographic regions in the United States. The regional councillor serves as the region's representative on the Board of Directors. If the regional councillor is absent from a Board of Directors meeting, the associate councillor may represent the region in place of the councillor, but the associate councillor does not have a vote. The councillor from each region is responsible, along with the president and the Executive Director, for coordinating regional activities to transact the business of the OPTN.

#### **C. At-Large Directors**

The Board must ensure that At-Large Directors represent the following categories:

- Transplant physicians and surgeons. Approximately 50 percent of the voting Directors will be surgeons or physicians directly involved in organ transplantation or donation.

- Non-physician transplant professionals, including transplant coordinators and individuals representing organ procurement organizations (OPOs) and transplant hospitals.
- Histocompatibility professionals.
- Individuals served by the OPTN, including transplant candidates, recipients, organ donors and their family members. At least 25 percent of the Directors will come from this category. These members should represent the minority and gender diversity of this population.
- Voluntary health organization representatives.
- At least one pediatric specialist.
- Non-transplant professionals, including professionals from law, theology, ethics, health care financing, public health, social and behavioral sciences, and labor and management unrelated to health care.

Directors representing transplant candidates, recipients, donors, and family members are required to certify that they are not employees of, or do not act on behalf of, OPOs, transplant hospitals, voluntary health organizations, transplant coordinators, histocompatibility professionals, or other non-physician transplant professionals. The Board of Directors may, however, waive this requirement for as many as 50 percent of these Directors.

The immediate past president of the OPTN Board of Directors is a member of the Board for a one-year term following the term as president.

## **2.2 Election**

The voting Directors must approve by majority vote of those present a slate of nominees to be included on the national ballot for the annual meeting. All voting Directors are elected by vote of OPTN members with voting privileges and member electors. The OPTN members and member electors vote, either in person or by proxy, at the annual meeting when a quorum is present. Voting Directors may also be elected at any special meeting of the members if the Board of Directors is being expanded, or if a Director must be replaced for any reason.

Each OPTN member and member elector has only one vote for each Director position.

### **A. Election of Officers**

The president and vice president are elected by vote of OPTN members each year. The treasurer is elected in odd-numbered years. The secretary and the Vice President of Patient and Donor Affairs are elected in even-numbered years. For more information, see *Article VI: Officers*.

### **B. Election of Regional Councillors**

Each OPTN region must elect an associate councillor, according to *Article 9.4: Regional Elections*. Unless otherwise determined by the nominating region, the associate councillor will subsequently become the region's nominee for regional councillor. The regional councillor nominee will be included on the national ballot of candidates for the Board of Directors.

### **C. Election of At-Large Directors**

Members with voting privileges and member electors will elect At-Large Directors by majority vote at the annual meeting.

## 2.3 Terms

All Director terms begin on July 1 following the annual meeting to elect the Board of Directors.

### A. Officer Terms

The president and vice-president serve one-year terms. The president and vice-president may not serve consecutive terms, except in the case of a vacancy in the office of president. If the vice president becomes president due to a vacancy, the vice president will be eligible for one succeeding one-year term as president.

The treasurer, secretary, and the vice president of patient and donor affairs serve two-year terms. These officers may serve consecutive terms.

The Board of Directors may not extend the term of an officer.

### B. Regional Councillor Terms

Regional councillors serve for a term of two years. Regional councillors must reside or be employed in the region they represent at all times during their term.

Regional councillors cannot serve consecutive terms in the regional councillor role, except when appointed by a majority of voting Directors to serve for up to one year before or after their term as regional councillor to fill a vacancy in their respective region.

### C. At-Large Director Terms

At-Large Directors will serve for a term of two years, with exceptions as noted below.

These At-Large Directors serve three-year terms:

- Transplant candidates.
- Transplant recipients.
- Organ donors.
- Family members of transplant candidates, recipients or organ donors.
- Representatives of voluntary health organizations.
- Representatives of the general public.

The Board of Directors may extend the term of an At-Large Director for one year, by majority vote of all voting directors present at the meeting. An At-Large Director's term may not be extended more than two consecutive times.

## 2.4 Vacancies

Except in the case of a vacancy in the office of president, the Board of Directors may fill a vacancy by appointing a Director by majority of all voting Directors for the unexpired portion of the Director's term.

If there is a vacancy in the office of president, the vice president will become president and will serve in that role for the unexpired portion of the term.

## **2.5 Removals**

The Board may remove a director for any reason with at least two-thirds vote of all Directors at any regular or special meeting of the Board of Directors.

## **2.6 Meetings**

The OPTN Board of Directors will hold regular meetings at least twice each year at a time and location selected by the Executive Director. The OPTN Board of Directors will hold one of these meetings in the Washington, D.C. metropolitan area, which includes Richmond, VA. The Executive Director or the president may call other regular or special meetings as it considers necessary. The Board may also call a special meeting with at least 25 percent of voting Directors submitting a written request to the Executive Director.

The OPTN Board of Directors must ensure that meetings are open to the public. However, the Board of Directors may hold closed sessions for discussions involving confidential medical peer review matters including OPTN membership approval, credentials, monitoring, or disciplinary matters as defined in the OPTN contract. The Board may also hold closed sessions for discussing matters involving individuals where an open meeting would compromise their privacy.

Representatives from the Federal Government serving on the Board of Directors, or their chosen representatives, will be included in closed sessions of OPTN meetings.

### **A. Notice of Meetings**

Approximately two weeks prior to a regular meeting, the OPTN Contractor must provide the Directors written notice, including information on the date, time, place, and agenda for the meeting. The Executive Director must distribute the Board of Directors meeting agenda to OPTN members at least 10 days before the date of the meeting.

A Director who signs a waiver of notice at any time will be exempt from the requirement of written notice. A Director who attends a meeting is assumed to have had adequate notice of the meeting unless the Director attends only to object that the meeting is not lawfully convened.

### **B. Quorum**

Fifty percent of the voting Directors constitute a quorum for transacting business at any meeting of the Board.

The following Directors do not count toward the quorum requirements specified in these Bylaws:

- Individuals serving on the Board of Directors as representatives of the U.S. Department of Health and Human Service (HHS)
- The OPTN Executive Director

### **C. Board Actions**

When a quorum is achieved, a majority vote of the voting Directors present is required to act at the meeting. There are two exceptions to the majority requirement:

1. When different voting requirements are defined in the Bylaws.
2. When an amendment to the Bylaws requires approval by a majority of *all* of the voting Directors, not just those present at the meeting.

#### **D. Actions without a Meeting**

The Board may take action without a convened meeting if there is unanimous written consent of all voting Directors. In order for actions to be taken without a meeting, all Directors must vote on the action and the vote must be unanimous.

### **2.7 Conflicts of Interest**

It is the OPTN policy that all Directors avoid conflicts of interest and the appearance of conflicts of interest. It is recognized that all Directors are directly or indirectly involved in organ donation, procurement and transplantation, and that the OPTN benefits from their collective expertise and experience in the development and implementation of OPTN policies.

However, issues that involve certain institutions or individuals may involve conflicts of interest. Directors must disclose employment or activities that might provide personal or financial gain related to the outcomes of matters affecting the OPTN and to act as required to avoid a conflict or the appearance of a conflict of interest. Avoiding conflicts of interest or the appearance of conflicts of interest may require that a Director abstain from voting on a matter or leave the room during discussion of the matter after providing relevant information to the Board.

### **2.8 Relationship of the OPTN Board and the OPTN Contractor's Board**

When the OPTN contract requires it, the OPTN Board of Directors will be elected in parallel with and using the same procedures as the OPTN Contractor's Board of Directors, resulting in identical memberships. This enables the OPTN Contractor to perform tasks required by the OPTN contract under the authority of the OPTN Board of Directors.

The Board of Directors will convene as the OPTN Board to conduct OPTN business and the OPTN Contractor Board to conduct OPTN Contractor business. Activities of the Board of Directors, while acting as the OPTN Board, will be limited only to activities and business of the OPTN. To accomplish this, separate agendas or sections within a combined agenda will identify if an item is OPTN business or OPTN Contractor business. Consistent with this process, OPTN Committees are appointed in parallel with OPTN Contractor Committees and operate under these same procedures.

## **Article III: Nominating Committee**

The Nominating Committee will recommend candidates for election as officers and Directors.

### **3.1 Composition**

The Nominating Committee is appointed by the president and will have no more than 12 voting members. With the exception of the past president directly preceding the immediate past president, the Nominating Committee will be selected from voting Directors.

The Nominating Committee will include:

- The president
- The Immediate Past president
- The past president directly preceding the Immediate Past president
- The vice president
- The vice president of patient and donor affairs
- One histocompatibility laboratory representative
- One OPO representative
- One transplant coordinator representative
- One patient representative
- One public representative (including organ donors and recipients, family members, or voluntary health organization representatives)

Two additional Nominating Committee members will be selected from *any* of the following voting Directors:

- Regional councillors
- A thoracic transplant Representative
- A minority transplant Representative
- Medical/scientific Organization members
- At-large Representatives

The following serve *ex-officio* and do not have a vote on the Nominating Committee:

- The Executive Director
- The U.S. Department of Health and Human Services (HHS) Project Officer for the OPTN Contract and the Director of the Division of Transplantation, or representatives they designate

### **3.2 Vacancies**

With the exception of vacancies in officer positions, the OPTN President will appoint Directors to fill vacancies on the Nominating Committee. If the vacancy is an officer position, the newly elected officer will be automatically designated as a Nominating Committee member.

### **3.3 Conflicts of Interest**

Nominating Committee members must avoid conflicts of interest and the appearance of conflicts of interest. The Nominating Committee will be held to the same standard as the Board of Directors and will deal with potential conflicts of interest according to *Article 2.7: Conflicts of Interest* of these Bylaws.

## **Article IV: Executive Committee**

The Executive Committee, as directed by the president who serves as its Chair, performs the following tasks:

- Continues the work of the Board of Directors without the necessity of convening the entire Board.
- Considers any issues that require expedited action between meetings of the Board of Directors.
- Provides advice to the Board.

### **4.1 Authority**

The Executive Committee can approve two types of actions:

1. Interim actions, which are immediately in effect unless otherwise stated in the resolution and remain in effect until the next Board meeting. The entire Board must approve the interim action at the next board meeting to make it permanent.
2. Final actions, which are as binding and enforceable as those approved by the entire Board of Directors, unless the Board specifically limits the Executive Committee from taking the action.

The president has discretion to defer matters for any reason until they can be considered by the entire Board.

### **4.2 Composition**

The Executive Committee is composed of no more than 12 individuals selected from the Board of Directors so that the Executive Committee is made up of:

- Approximately 50 percent transplant surgeons and transplant physicians directly involved in transplantation.
- At least 25 percent transplant candidates, recipients, donors and their family members.
- At least one member of the general public.

The Executive Committee includes the following Directors:

1. The president, who serves as the Chair of the Executive Committee
2. The Immediate Past president
3. The Vice-president
4. The Vice-president of Patient and Donor Affairs
5. The Secretary
6. The treasurer
7. A minority transplant professional representative

Five other members of the Executive Committee are selected so that there is at least one member from each of the following four categories:

1. OPO Representatives
2. Transplant Coordinator Representatives

3. histocompatibility laboratory Representatives
4. Public Representatives (including organ donors and recipients, family members or voluntary health organizations)

The following serve *ex-officio* and do not have a vote on the Executive Committee:

- The Executive Director
- The U.S. Department of Health and Human Services (HHS) Project Officer for the OPTN Contract and the Director of the Division of Transplantation, or a representative they designate

#### **4.3 Selection**

The officers of the Board of Directors are automatically designated as Executive Committee members. The remaining five Executive Committee members will be elected by a vote of Directors from the category they will represent. For example, Directors representing OPOs elect the individual who will serve as the OPO representative on the Executive Committee.

#### **4.4 Term**

Executive Committee members serve terms of one year, except for those designated members who are officers of the Board of Directors. Officers who are members of the Executive Committee serve for the duration of their term in office.

#### **4.5 Removals and Vacancies**

With the exception of officers, the Board of Directors may remove a Director from the Executive Committee for any reason with a majority vote of Directors present at a meeting. The Board may only remove an officer from the Executive Committee by removing the officer from the Board as outlined in 2.5 *Removals*.

If a vacancy occurs, the voting Directors may fill a vacancy on the Executive Committee for the unexpired portion of a term. If the vacancy is an officer position, the newly elected officer will be automatically designated as an Executive Committee member for the unexpired portion of the term. If the vacancy is within the remaining five Executive Committee members, the replacement will be determined by the process outlined in *Article 4.3: Selection*.

#### **4.6 Conflicts of Interest**

Executive Committee members will avoid conflicts of interest and the appearance of conflicts of interest. The Executive Committee will be held to the same standard as the Board of Directors and will deal with potential conflicts of interest according to *Article 2.7 Conflicts of Interest* of these Bylaws.

## **Article V: Executive Director**

The OPTN Contractor must employ a full time Executive Director who is appointed by the Board of Directors and reports to the president.

### **5.1 Responsibilities**

The Executive Director has the following responsibilities:

1. Coordinates the activities of the Permanent Standing Committees.
2. Maintains the current list of names and addresses of the Directors and members.
3. Keeps the financial records of the OPTN Contractor and accounts for the revenues and expenses of the OPTN, which are subject to review by the treasurer and available to any Director upon request.

### **5.2 Term**

The Board of Directors determines the term of the Executive Director. At the discretion of the Board, the Executive Director may serve consecutive terms.

### **5.3 Conflicts of Interest**

The Executive Director must avoid conflicts of interest and the appearance of conflicts of interest. The Executive Director will be held to the same standard as the Board of Directors and will deal with potential conflicts of interest according to *Article 2.7: Conflicts of Interest* of these Bylaws.

## **Article VI: Officers**

The officers of the OPTN are the:

1. President
2. Vice president
3. Vice president of patient and donor affairs
4. Treasurer
5. Secretary

### **6.1 President**

The president will preside at all meetings of the members and Directors.

### **6.2 Vice President**

The vice president is the president-elect of the OPTN and serves as an *ex-officio*, non-voting member of the Membership and Professional Standards Committee (MPSC). If the president is absent, the vice president performs all duties required of the president, as well as any other duties required by the Board of Directors or these Bylaws.

### **6.3 Vice President of Patient and Donor Affairs**

The vice president of patient and donor affairs represents the interests of patients, donors and their family members on the Board of Directors.

### **6.4 Treasurer**

The treasurer will regularly review the finances of the OPTN, serve as Chair of the Finance Committee and report to the Board of Directors regarding the financial condition of the OPTN at the Board's request. The treasurer must ensure that an annual audit and report of OPTN finances are completed, and provide copies of both to the Directors and Executive Director. The treasurer is also an assistant secretary and has the authority to sign in place of the secretary when the signature of the secretary of the OPTN is required on any document.

### **6.5 Secretary**

The secretary attends all meetings of the members and Board of Directors, and keeps the minutes of the business transacted at these meetings. Whenever the signature of the secretary of the OPTN is required, the treasurer or Executive Director has the authority to sign for the secretary.

### **6.6 Assistant Secretaries**

One or more assistant secretaries may perform all duties required of the secretary if the secretary is absent for any reason.

### **6.7 Other Duties**

The officers of the OPTN will have other powers and duties that are designated to them by the Board of Directors, or as required by law.

## 6.8 Resignation

An officer may resign at any time by giving written notice to the Executive Director. If an officer vacancy occurs, the voting Directors may appoint a new officer according to *Article 2.4 Vacancies*.

## 6.9 Conflicts of Interest

Officers must avoid conflicts of interest and the appearance of conflicts of interest. Because officers are also Directors, they will be held to the same standard for conflicts of interest as the Board of Directors according to *2.7: Conflicts of Interest* of these Bylaws.

## **Article VII: Permanent Standing Committees**

The OPTN will have the following permanent standing Committees:

- Ethics
- Histocompatibility
- Kidney Transplantation
- Liver and Intestinal Organ Transplantation
- Living Donor
- Membership and Professional Standards
- Minority Affairs
- Operations and Safety
- Organ Procurement Organization
- Pancreas Transplantation
- Patient Affairs
- Pediatric Transplantation
- Policy Oversight Committee
- Thoracic Organ Transplantation
- Transplant Administrators
- Transplant Coordinators

The Committees are advisory to the Board of Directors, which makes the final decisions of the OPTN. The standing Committees will provide initial review and analysis of proposed policies and initiatives based on their collective expertise and unique perspectives, and present their recommendations to the Board of Directors.

Committees may also be advisory to each other when Committee interest and expertise overlap. When Committees evaluate proposals jointly, they should present to the Board of Directors either a common recommendation or a report that summarizes the continued disagreement.

Committees may have additional responsibilities as defined by the OPTN Bylaws and Policies. Committees' role in developing policies and standards is further defined in *Article XI: Adoption of Policies* of these Bylaws.

### **7.1 Composition of Standing Committees**

Each standing Committee must be represented by each of the OPTN geographic regions. For more information about the OPTN regions, see *Article IX: Regions* of these Bylaws.

All standing Committees should have at least one representative from each region as well as representatives from the following:

- Transplant hospitals

- OPOs
- Transplant coordinators
- Transplant candidates, recipients, donors, or their family members

In addition, the Histocompatibility Committee should have at least one histocompatibility laboratory representative from each region, and histocompatibility laboratories will also elect the vice chair to serve on the Histocompatibility Committee.

The vice president, as incoming president, will appoint representatives to the Committees from a list of nominations received from the regional councillors. Committees will, to the extent practical, include racial and gender representation reflecting the diversity of those served by the OPTN.

The U.S. Department of Health and Human Services (HHS) Project Officer for the OPTN contract and the Director of the Division of Transplantation, or representatives they designate, serve *ex-officio* and do not have a vote on the Committees.

Committee members are usually appointed to only one standing Committee at a time, but the vice president may appoint members to multiple Committees to enhance communication between Committees, or for any reason that may increase knowledge and productivity of the Committees.

## **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 three years, except for Membership and Professional Standards Committee (MPSC) members, who serve two-year terms. When appointing permanent standing Committee members, the vice president may also:

- Appoint up to one-third 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 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.

## 7.4 Meetings

Permanent standing Committees will meet as necessary to carry out projects approved by the Board of Directors. Committee meetings are typically open to the public. However, the Committees will hold closed sessions for discussions involving confidential matters including OPTN membership approval, credentials, monitoring, or disciplinary matters as defined in the OPTN contract. Matters involving individuals where an open meeting would clearly compromise their privacy will also be reviewed in closed sessions.

The U.S. Department of Health and Human Services (HHS) Project Officer for the OPTN contract and the Director of the Division of Transplantation, or representatives they designate, may attend all closed sessions of OPTN meetings.

## 7.5 The Policy Oversight Committee (POC)

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

### A. Composition of POC

The POC will be comprised of the Vice Chairs of each of the Committees, or a representative of each Committee appointed by the vice president, and other individuals as needed.

### B. Ex-officio Representation

The Policy Oversight Committee will also have non-voting, *ex-officio* members from the Division of Transplantation of the HHS and the 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.

### C. Terms of POC Members

All POC members, except the Chair or Vice Chair, serve for terms equal to the term they are serving on the Committee they are representing. POC terms begin on July 1.

## 7.6 Finance Committee

In addition to the permanent standing committees listed above, the OPTN will have a Finance Committee to assist in the governance of the OPTN.

The Finance Committee will report to the Board. The Finance Committee will have members,

composition, terms, and duties, as may be determined by the President in consultation with the Board of Directors. The President may appoint any number of non-voting Advisors to the Finance Committee subject to approval by the Board of Directors for terms the President may deem appropriate.

## **7.7 Conflicts of Interest**

All OPTN Committee members must avoid conflicts of interest and the appearance of conflicts of interest. Committee members will be held to the standard for conflicts of interest as described in *Article 2.7: Conflicts of Interest* of these Bylaws.

## **Article VIII: Financial Considerations**

### **8.1 Fiscal Year**

The fiscal year of the OPTN will begin on October 1 and end on the following September 30.

### **8.2 Reserve Fund**

The OPTN Board of Directors will establish and maintain a Primary Account and a Reserve Account as described in the OPTN Contract. The Reserve Account will be available to pay allowable OPTN operating costs consistent with the terms of the OPTN Contract in the event of insufficient funds in the Primary Account. The Reserve Account will also be available for OPTN program activities identified by the OPTN Board of Directors as critical to the OPTN, but that could not be implemented with available Primary Account funds.

#### **A. Reserve Fund Creation and Purpose**

The Reserve Account is funded by a designated amount from OPTN registration fees. The Finance Committee will regularly assess the Reserve Account, and make recommendations to the Board of Directors on the amount of the Reserve Account and the designation of OPTN registration fees to be directed toward reserve funding. The Board of Directors may authorize additional transfers from the Primary Account to the Reserve Account at any time. If reserve funds are used due to insufficient funds in the Primary Account, the reserve funds will be replenished from the Primary Account as funds become available.

#### **B. Reserve Account Funds**

The Reserve Account will be fully funded when it contains funds equal to three months of average budget operating expenses based on the then-current fiscal year. Reserves may be held in several accounts with multiple financial institutions, and may contain cash or other short term investments.

#### **C. Use of Reserve Account Funds and Notification**

1. The Board will approve a revenue estimate for each fiscal year based on the projected number of registrations, the amount of the registration fee, and the amount of any federal appropriated funds.
2. In the event of a funding shortfall, funds may be withdrawn from the Reserve Account if two conditions are met:
  - a. A revenue shortfall equal to at least 3 percent of OPTN revenue for a fiscal year is projected to occur. The Executive Director will report to the Board the reason for the projected shortfall and the new revenue estimate for the fiscal year
  - b. The amount of funds in the Primary Account is less than or equal to one month of average operating expenditures

If both conditions are met, the Executive Director may transfer the lesser of one-half of the amount of the projected shortfall or one-half of the amount of the balance of the Reserve Account to the Primary Account.

At least 72 hours prior to any transfer from the Reserve Account, the Executive Director will provide written notification to the Board of Directors of the planned transfer.

3. Funds may also be withdrawn from the Reserve Account if the HRSA Contracting Officer Representative (COR) and the Executive Director, with approval by the OPTN Executive Committee, mutually agree in writing to the transfer of funds.

## **Article IX: Regions**

### **9.1 Structure**

There are 11 OPTN geographic regions in the United States. The OPTN regions provide a platform for sharing ideas and information about organ procurement and transplantation in a smaller forum. OPTN members belong to the region where their principal office or residence is located. The regions are:

- Region 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont
- Region 2:** Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO.
- Region 3:** Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi and Puerto Rico
- Region 4:** Oklahoma and Texas
- Region 5:** Arizona, California, Nevada, New Mexico and Utah
- Region 6:** Alaska, Hawaii, Idaho, Montana, Oregon and Washington
- Region 7:** Illinois, Minnesota, North Dakota, South Dakota and Wisconsin
- Region 8:** Colorado, Iowa, Kansas, Missouri, Nebraska and Wyoming
- Region 9:** New York and Western Vermont
- Region 10:** Indiana, Michigan and Ohio
- Region 11:** Kentucky, North Carolina, South Carolina, Tennessee and Virginia

### **9.2 Meetings**

Each region holds at least two meetings per year. The purpose of these meetings is to:

- Exchange information.
- Discuss and comment on issues distributed for public comment during the OPTN policy development process.
- Nominate regional councillors and Associate regional councillors.
- Address any matters of interest to the region.

Proposals developed at regional meetings are sent to the national Committees for consideration. The Committees, which include representatives from each region, then present the proposals to the Board of Directors for approval or rejection.

### **9.3 Regional Voting Privileges**

Members and member electors with voting privileges who reside in a region will have one vote on each OPTN regional matter, including the election of councillor and associate councillor. Transplant hospital, OPO, histocompatibility, medical/scientific, and public organization member representatives will belong to a region according to the location of the member's principal offices.

Any individual who is currently serving on an OPTN Committee and who is not employed by or on the medical staff of a transplant hospital, histocompatibility laboratory, OPO, medical/scientific or public organization member will also have regional voting privileges.

## 9.4 Regional Elections

Members, member electors, and individuals with voting privileges in each region will elect a regional councillor and an associate councilor, using one slate for councillor and a second slate for associate councillor. Unless otherwise determined by the region, the subsequent elections will include only a slate for a new associate councillor, with the current associate councillor automatically becoming the councillor.

### A. Regional Councillor Election

The regional councillor serves as the region's representative on the Board of Directors. The councillor from each region is responsible, along with the president and the Executive Director, for coordinating regional activities to transact the business of the OPTN. The regional councillor is elected according to *Article 2.2.B: Election of Regional Councillors*.

### B. Associate Councillor Election

Each region determines the guidelines for electing associate councillors. The associate councillor serves on the MPSC for a two-year term that begins July 1 following the regional election.

Associate councillors cannot serve consecutive terms, except when appointed by the OPTN vice president to fill an associate councillor vacancy. If the associate councillor is appointed to fill a portion of another associate councillor's term due to a vacancy, then the associate councillor will be eligible for one succeeding two-year term as associate councillor.

Associate councilors must reside in or be employed in the region they represent at all times during their term.

## 9.5 Review Boards (RRBs)

The OPTN establishes review boards to review requests for exceptions that are permitted by Policy. These review boards provide confidential medical peer review of transplant candidates placed on the waiting list at a more urgent status than the standard listing criteria justifies. As part of these reviews, review boards may perform the following tasks:

- Review justification forms submitted by the transplant hospital that document the candidate's current condition and decide if the requested status is appropriate.
- Refer transplant hospitals to the appropriate OPTN Committee for review of candidates listed and transplanted at an inappropriate status. The Committee may then, if necessary, refer the hospital to the Membership and Professional Standards Committee (MPSC).
- Serve other peer review functions as determined by the Board of Directors.

Review boards are formed under the direction of the Committees and Board of Directors. Review boards can operate and perform peer review functions as determined by the Board of Directors. The Board of Directors and Committees may establish other guidelines for Review Board organization and function as necessary.

## **Article X: Amendment of Charter and Bylaws**

### **10.1 Voting Requirements**

The Board of Directors can amend the Charter or Bylaws with a majority vote of all Directors. An amendment passed by the Board of Directors is in effect until the next annual meeting of members. Every amendment to the Charter or Bylaws approved by the Board of Directors must be confirmed by a majority vote of a quorum of members present at the annual meeting. If the amendment is not confirmed at the annual meeting, the amendment is repealed, effective from the date of the annual meeting.

### **10.2 Notice**

Each Director must receive notice of any meeting where there will be a proposal to amend the Charter or Bylaws. The notice will be sent to the address on file with the Executive Director, or by any method that, in the opinion of the Executive Director, gives adequate notice to the Directors. Notices for meetings must be sent no more than 60 days or no fewer than 10 days before the date of the meeting. The proposed amendment must be provided with the meeting notice.

### **10.3 Non-substantive Changes to Bylaws**

The OPTN Contractor may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any of these changes made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

## **Article XI: Adoption of Policies**

The OPTN Policies and OPTN Bylaws are the policy documents that govern the allocation, procurement, transportation and transplantation of donated organs. The Board of Directors is responsible for approving and implementing policies that reflect the mission of the OPTN. The Board fulfills this responsibility with input from the OPTN membership and other interested individuals. The OPTN policy development process includes these main steps:

1. Issues are presented to one or more Committees for consideration.
2. The Committee creates a policy proposal.
3. The proposal is distributed to the public, including members of the transplant community, for review and comment.
4. The Committee considers and responds to comments, and then develops a final policy proposal.
5. The final proposal is sent to the Board of Directors for a vote. The Board of Directors may adopt, amend and adopt, or reject the proposal. The Board may also return the proposal to the Committee for further deliberation.
6. The OPTN Contractor provides notice to the transplant community that the Board of Directors has approved changes to OPTN policy, and takes the necessary steps to implement the changes.
7. Once the policy has been adopted and implemented, it is periodically evaluated for its impact and effectiveness.

### **11.1 Creating and Submitting Policy Proposals**

Committees develop proposals for new policies or changes to existing policies and submit them to the Board of Directors for consideration. Committees developing proposals may also request review and comment from one or more additional Committees if necessary. For more information about OPTN Committees, see *Article VII: Permanent Standing Committees* of these Bylaws.

Committees analyze policy proposals using select data to measure the effect of the proposal on the transplant community. The analysis includes baseline data that reflects how current policy is performing as well as projected outcomes to estimate the impact of the policy proposal. Data, analysis, and other information requested by the Committees are provided by the OPTN Contractor and Scientific Registry of Transplant Recipients (SRTR) contractor, as specified in their contracts with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS).

Policy proposals include a summary that provides background information to explain the purpose of the proposal and the issues that were considered in developing the proposal.

#### **A. The Public Comment Period**

The public, including the transplant community, is usually included in the OPTN policy development process through the public comment process. Proposals to change organ allocation or membership requirements require public comment. However, some policy proposals do not require public comment, including:

- Proposals that clarify or correct existing policy rather than changing the intent or adding to the policy.

- Proposals that reflect administrative or non-substantive procedural changes that do not change the intent of the policy or do not impact the operations of the transplant community.

The public comment period is usually 45 days.

Proposals issued for public comment are distributed in the following ways:

1. Posted to the OPTN website or mailed to all OPTN members and anyone who requests to be placed on the list.
2. Provided at regional meetings of the members.
3. Provided at meetings of interested Committees.

Comments received during the public comment period will be reviewed and addressed by the sponsoring Committee. Comments received after the end of the set public comment period may be reviewed and addressed at the discretion of the Chair of the sponsoring Committee.

Based on the comments received, the Committee may make modifications to the proposal, including withdrawal of the proposal. Should the Committee choose to recommend the policy proposal to the Board, the proposal will be updated to include the public comments and the Committee's responses and then presented to the Board of Directors as a final proposal.

## **B. Mandatory and Non-mandatory Policies**

In developing policy proposals, the sponsoring Committee determines if the policy should be one of the following:

- Mandatory, or designated by the Secretary of Health and Human Services (HHS) as a federal regulation defined by the OPTN Final Rule according to the requirements of *Section 1138* of the Social Security Act.
- Non-mandatory, but binding as required by the OPTN Bylaws and agreed to by all OPTN members in the membership contract.

The OPTN Final Rule, *section 121.11(b)(2)* makes submission of data to the OPTN by OPO and transplant hospital members mandatory, and failure to submit the required data is considered by HRSA to be a violation of OPTN membership requirements.

The sponsoring Committee can recommend that a policy be made mandatory, and the Board of Directors must support the recommendation. The policy must then be presented to the Secretary of HHS for approval as mandatory policy. Recommendations from the Board to make a policy mandatory must be approved by the Secretary of HHS or the policy remains non-mandatory.

No OPTN policy will be subject to enforcement as specified in *section 1138* of the Social Security Act until approved by the Secretary of HHS. Compliance with OPTN policies determined to be non-mandatory will be monitored by the OPTN according to these Bylaws.

Policies recommended for adoption into HHS regulation might include those necessary for the administration of other programs related to organ procurement and transplantation in the

Department of HHS. The Secretary may solicit guidance from the Secretary's Advisory Committee on Organ Transplantation in accordance with the OPTN Final Rule.

## 11.2 Submitting Policy Proposals to the Board of Directors

After the sponsoring Committee completes the policy proposal and any necessary public comment process, the Committee submits the proposal to the Board of Directors. The Board of Directors may take *any* of the following actions:

- Approve the proposal without amendment.
- Amend and then approve the proposal.
- Reject the proposal.
- Refer the proposal back to the sponsoring Committee or to other Committees for additional consideration.
- Any other action the Board decides is appropriate.

These actions may also be considered and implemented by the Executive Committee between meetings of the Board of Directors. For more information, see *Article IV: Executive Committee* of these Bylaws.

Policies approved by the Board of Directors with or without amendment and recommended as non-mandatory will be implemented as described below.

Policies approved by the Board of Directors and recommended to be enforced as mandatory policies are forwarded to the Secretary of HHS for review and comment according to the OPTN Final Rule, *section 121.4(b)(2)* at least 60 days before implementation.

## 11.3 Notification of Policy Updates

Some policies approved by the Board of Directors will require an update to the UNet<sup>sm</sup> computer allocation and matching system. After the system update is completed to reflect the new policy, the OPTN contractor will provide notice to OPTN members and the Secretary of HHS through mailings, newsletters, or the Internet. Policy updates will also be posted to the OPTN web site.

## 11.4 Ongoing Policy Review

Committees periodically evaluate OPTN policies to determine if the policies are meeting stated objectives and remain current with scientific and technological advances. Depending on the outcomes of these assessments, proposals for additional policies or changes to existing policies may be proposed.

## 11.5 Non-substantive Changes to Policy

The OPTN Contractor may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy

- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any corrections made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

## 11.6 Adoption of Policies

New policy or changes to existing policy adopted by the Board of Directors may periodically be incorporated into these Bylaws by amendment to the Bylaws. Members must comply with all policies after adoption by the Board of Directors and after receiving written notice, even if the policies have not been incorporated as amendments to these Bylaws.

## 11.7 Emergency Actions

Policy proposals that meet *at least one* of the following criteria may be adopted by the Board of Directors prior to public comment:

- A proposal that is necessitated by a pending statutory or regulatory change.
- A proposal that is required due to an emergent public health issue or patient safety factors.
- A proposal that is necessitated by a new medical device or technology that affects organ allocation,

Instead, the policy development process for these proposals will require *all* of the following steps:

1. The sponsoring Committee submits the proposal according to *11.2 Submitting Policy Proposals to the Board of Directors*.
2. The proposal designates a future date upon which the policy will expire, not more than 12 months beyond the policy's effective date.
3. The policy is distributed for public comment no more than 6 months after approval. This public comment period can be shorter than the normal public comment period but must be at least 30 days.

## 11.8 Expedited Actions

Policy proposals that are expected to be non-controversial may be adopted according to the following process:

1. The Board approves a new or revised policy that includes specific policy language defining components of the policy that will be eligible for future expedited updates as well as the anticipated frequency of updates.
2. At a later date (as directed by the policy timeline), the sponsoring Committee develops a proposal for expedited action as stipulated in the policy.
3. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
4. The sponsoring committee considers public comments and recommends final adoption of the proposal.
5. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or 4 members of the Board of Directors, then the sponsoring Committee will notify the Executive Committee of the objections and proceed with the normal OPTN policy development process.
6. If the specified number of objections in #5 above are not received during the public comment period, then the process will proceed as follows:
  - a. If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership, unless a different date is specified.

- b. If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to *11.2 Submitting Policy Proposals* to the Board of Directors.

## 11.9 Developing Organ Allocation Policies

Policy proposals affecting organ allocation must specify the organ or combination of organs addressed in the policy and summarize how the proposal meets requirements of the OPTN Final Rule, *42 CFR Part 121*.

### A. Guidelines for Organ Allocation Policies

Committees developing or evaluating OPTN organ allocation policies should consider *all* the following:

1. The criteria used in listing and removing candidates on the waiting list, including the medical basis and analyses used in the development of the criteria.
2. Accessibility and socio-economic equity, including how the proposal addresses ethnic barriers to transplantation, ethnic disparities on the waiting list, pediatric access to transplantation, and any barriers to transplantation resulting from economic factors.
3. Processes to promote and assess policy compliance, including prospective review, retrospective review, educational measures, and any actions that might be recommended to the Secretary of HHS in the event of non-compliance.
4. Provisions to address patients on the waiting list under the former policy to ensure their equitable treatment under the policy proposal, including anticipated impact of the proposal on these patients and continuation of their former priority, within reasonable limits and to the extent possible.
5. Performance indicators to be used to evaluate the policy's effect including how performance will be measured, the basis for measurement, baseline data for evaluating performance of the current policy, projected data showing expected benefit from the proposal, and a plan for periodic review to assess effectiveness of the policy in achieving its goals.
6. Systems that test methods of improving organ allocation data variances, including an assessment of whether the variances are accompanied by a research design and include data collection, analysis plans, time limitations, standards for approving variances, and a determination of whether existing variances would continue under the policy proposal.
7. The impact on the organ allocation system, including:
  - Categories for prioritizing transplant candidates and the medical basis (including medical urgency), supporting research, and current medical practice.
  - Geographic units used for allocating organs, including how criteria such as patient residence or listing location may be overcome by geographic allocation unit definition while considering organ ischemic time, logistical matters, and the availability of specialized transplant and post-transplant care.
  - Overall allocation protocol, demonstrating how organs are allocated according to medical urgency or other relevant categories within geographic units using sound medical judgment, the best use of donated organs, physician judgment in declining organ offers or use for the potential recipient, suitability for the specific organ or combination of organs, avoidance of organ waste and futile transplants, promotion of patient access to transplantation, efficient management of organ placement, periodic review and revision

as appropriate, and disassociation with candidate's place of residence or place of listing as feasible in consideration of the previously listed elements.

## **B. Organ Allocation Policy Data Analysis**

In developing organ allocation policy, data analysis should include:

- The effect on transplant programs that perform different transplant volumes.
- Organ-specific analyses within transplant programs.
- Risk-adjusted total life-years pre- and post-transplant.
- Risk-adjusted post-transplant patient and graft survival rates.
- Risk-adjusted waiting time.
- Risk-adjusted transplantation rates.
- The performance of OPOs.
- The performance of the OPTN Contractor.
- Other data as determined by the reviewing Committees.

Review of data may result in additional questions and the need for further study and analysis, dismissal of the proposal, or formulation of a proposal by the Committee.

## **Appendix A: Membership Application and Review**

This appendix outlines the application process for membership in the OPTN. It includes information about completing the membership application, the application review process, and application approval for transplant hospital, organ procurement organization (OPO), histocompatibility laboratory, individual, Medical/Scientific, public organization, and business members.

For more information on membership types, terms, voting privileges, and responsibilities, see *Article I: Membership* of these Bylaws.

### **A.1 Applying for Membership in the OPTN**

The Membership and Professional Standards Committee (MPSC) reviews each application for membership and makes recommendations to the Board of Directors.

The Board of Directors makes all final decisions regarding membership and designated transplant program applications.

Every transplant hospital member must have current approval as a designated transplant program for at least one organ. Any hospital applying for transplant hospital membership must also submit the required application for approval as a designated transplant program for at least one organ.

Applications for OPTN Membership and designated transplant program approval must be submitted on the form provided by the OPTN Contractor, and signed by a representative of the applicant who can certify that the information, including any supporting documents, is accurate.

#### **A. Conditions for Application**

By submitting a signed application for membership in the OPTN, each applicant and member agrees to *all* of the following:

1. That any and all information collected as part of the application may be released to the Department of Health and Human Services (HHS). Members also agree that any and all information provided as part of the monitoring and enforcement of OPTN membership requirements, policies and Federal regulations may be released to HHS.
2. If an adverse ruling is made regarding membership or designated transplant program approval, the member will exhaust the administrative remedies provided in these Bylaws and applicable Federal regulations before resorting to formal legal action.
3. That the applicant has received and read the current OPTN Charter, Bylaws, and Policies and agrees to be bound by the terms of these documents during the application process and if granted membership.
4. That transplant hospital, OPO, and histocompatibility laboratory members will provide evidence of current liability insurance of at least one million dollars from an insurer that is either licensed or approved by the insurance regulatory agency of the state where the applicant's principal office is located. A current certificate of insurance must be available and provided to the OPTN Contractor on request. In place of liability insurance, the member can provide proof of coverage through a self-insurance fund, and must provide documentation that the fund provides equivalent coverage.
5. To accept the conditions of the Statement of Release and Immunity from Liability as written below.

#### **Statement of Release and Immunity from Liability**

As used in this section, the following definitions apply:

1. *OPTN Contractor and its representatives* means the corporation currently operating the OPTN under contract with HHS, its officers, its Board of Directors, its appointed representatives or employees, consultants, the Contractor's attorneys, assistants or designees, and all members, organizations or other persons who have any responsibility for obtaining or evaluating applicant or member qualifications or acting upon the application for membership or designated transplant program status. This includes any authorized representative of any of the entities or persons noted in this paragraph.
2. *A third party means* all individuals or government agencies, organizations, associations, partnerships and corporations, from whom information has been requested by the OPTN Contractor or its authorized representatives. This includes anyone who requests or receives information from the OPTN and its authorized representatives.

The following are conditions that apply to any applicant or OPTN member. An applicant accepts the following conditions throughout the application process, whether or not the applicant is granted membership or approval as a designated transplant program:

- a. To the fullest extent permitted by law, the applicant or member gives absolute immunity to, and releases the OPTN Contractor, its representatives, and any third party from any and all liability resulting from any acts, communications, reports, recommendations, or disclosures involving an applicant or member. This includes disclosures to, from, or by any third party, including other members, concerning activities within the scope of the OPTN Contract including but not limited to:
  - i. Applications for membership or designation as a transplant program;
  - ii. Proceedings regarding monitoring and enforcement of membership requirements, change in membership or designated transplant program status, termination of membership, or other policies of or regulations concerning the OPTN
  - iii. Other committee activities relating to the membership status or designated transplant program status of an applicant or member. This includes statements, investigations, materials provided, or inquiries, oral or written, relating to an applicant's or member's qualifications, as well as the review of all relevant records and documents
- b. Any act, communication, report, recommendation or disclosure, with respect to any applicant or member made in good faith and at the request of the OPTN Contractor and its representatives, anywhere and at any time, for the purposes described in (a) above are privileged to the fullest extent permitted by law as part of the OPTN medical peer review. The medical peer review privilege extends to any third parties who either supply or are supplied information and are authorized to receive, release or act upon the same.
- c. The immunity and release from liability provided in this section shall not apply to acts of willful misconduct by the OPTN Contractor and its representatives.

## **B. Initial Review of the Membership Application**

To initiate the review of any new membership application, the applicant must deliver a completed application, including all requested supporting documentation to the Chair of the MPSC, the Executive Director, or their designated representative. The MPSC will not accept applications for review that are incomplete or missing supporting documentation.

Designated staff of the OPTN Contractor will conduct a preliminary review of all submitted applications to ensure that they are complete. This initial review will occur for all application types.

New membership applications that are not completed correctly or are missing information will be considered incomplete. The OPTN Contractor will not forward incomplete applications to the MPSC for review. The MPSC Chair, the Executive Director, or their designated representative will notify the applicant if an application is incomplete and provide guidelines for correctly completing the application. It is ultimately the applicant's responsibility to obtain and submit the missing information necessary for the application to be reviewed.

### **C. MPSC Review of the Completed Membership Application**

The Board of Directors makes all final decisions regarding membership and transplant program applications. Before being considered by the Board, the MPSC reviews all applications and submits a written report with recommendations regarding the application to the Board of Directors. The MPSC Chair, or a chosen representative, may appoint an MPSC subcommittee of at least four MPSC members to review the completed application and supporting documentation. The MPSC subcommittee may make recommendations regarding applications for membership or approval as a designated transplant program. The MPSC subcommittee's recommendations are advisory to the MPSC and the Board of Directors.

#### **MPSC Subcommittee Review and Recommendation**

A unanimous decision of approval by the MPSC subcommittee reviewing the application will result in interim approval of the application. Interim approval means that the member may function as an OPTN member while awaiting review by the entire MPSC and the Board of Directors. A member granted interim approval does not have voting privileges on OPTN matters.

If any member of the MPSC subcommittee recommends rejection of the application, the applicant will not receive interim approval, and the application will be reviewed by the entire MPSC at its next meeting.

#### **MPSC Review and Recommendation**

All applications reviewed by the MPSC subcommittee are sent to the entire MPSC for review at its next meeting. Based on the review at this meeting, the Chair will submit a written report with recommendations regarding the application to the Board of Directors. This report includes:

1. The reason for each recommendation, supported by citations to the completed application and any other documentation considered by the MPSC.
2. All dissenting or minority views that differ from the final recommendation, also supported by citations to the completed application and any other documentation considered by the MPSC.

#### **Interim MPSC Approval of the Membership Application**

An application approved by the entire MPSC receives interim approval until final review by the Board of Directors. This approval is in effect until a final determination is made by the Board of Directors.

Interim approval will:

1. Grant the applicant OPTN membership or designated transplant program approval, as applicable.
2. Expire when and if the full Board rejects the interim action.

### **MPSC Rejection of the Membership Application**

The MPSC must offer the applicant an interview if the MPSC recommends that the Board of Directors rejects a membership application. The applicant may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as part of the membership application process will be held according to *Appendix L: Reviews and Actions*.

### **D. Final Board of Director's Review of the Membership Application**

When the MPSC recommends that an application be approved, the MPSC Chair will forward the MPSC's report and recommendation to the Board of Directors.

The Board of Directors will review the application and act on it during its next regular meeting if the following conditions are met:

1. The Board of Directors receives the recommendation from the MPSC at least 10 business days before the meeting.
2. A quorum is present at the meeting.

Any application not received at least 10 business days before the meeting will not be considered until the next regular Board meeting at which a quorum is present. If the MPSC gave the application interim approval, a decision to defer the matter will continue the interim approval until the next regular meeting of the Board of Directors where a quorum is present.

A majority vote of the Directors present at any meeting at which a quorum is present is required to approve a new member.

### **E. Appeals to the Secretary**

Applicants rejected for membership in the OPTN or for designation as a transplant program may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may deny the appeal or direct the OPTN to take action consistent with the Secretary's response to the appeal.

### **F. Geographically Isolated Transplant Program Applicants**

The MPSC may recommend to the Board of Directors the approval of a designated transplant program if the prospective program cannot satisfy the current key personnel requirements due to its geographical isolation. Geographically isolated applicants must demonstrate to the MPSC that the proposed key personnel have both a satisfactory level of transplant experience and an established history of transplant success for the specific organ type indicated in the application for designated transplant program status.

MPSC recommendation of approval of a geographically isolated program that is not otherwise qualified does not give interim approval to the prospective program. The designated transplant program status of a geographically isolated program that is not otherwise qualified is effective only upon approval of the Board of Directors.

For purposes of this provision, "geographically isolated" is defined as a program located entirely within a state or commonwealth noncontiguous with the mainland United States. This includes Alaska, Hawaii, and Puerto Rico.

## **A.2 Re-application after Rejection for Membership**

An applicant who has been denied OPTN membership or designated transplant program approval may re-apply for membership. A re-application is processed the same as the initial application and is evaluated based on criteria in effect when the re-application is submitted.

The applicant may be required to submit additional information to the MPSC or the Board of Directors to demonstrate that the issues resulting in the earlier rejection of the application have been resolved.

## **Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)**

### **B.1 OPO Compliance**

By accepting membership in the OPTN, OPOs agree to comply with all OPTN Obligations according to *Article 1.1.E: Member Compliance*.

If any regulatory agency takes a final adverse action against an OPO, the OPO must notify the OPTN Contractor in writing within 10 business days. The OPO must also provide all documents relating to the final adverse action to the OPTN Contractor.

### **B.2 OPO Performance Requirements**

The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area or OPO in question.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

1. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors - Expected per 100 donors < -10).
2. A ratio of observed to expected yield less than 0.90.
3. A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix L: Reviews and Actions*.

As part of this process, the MPSC may conduct a peer visit to the OPO at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to *Appendix L: Reviews and Actions*.

### **B.3 Quality Assessment and Performance Improvement (QAPI) Requirement**

- A. OPOs must develop, implement and maintain an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives.
- B. The OPO must document implementation of all elements of the QAPI plan.

## **B.4 Facilities and Services**

OPOs must have extensive facilities to be fully operational. OPOs must also provide a number of services as part of their daily operations. These required facilities and services are described in the sections that follow.

### **A. Transplant Hospital Relationship**

Each OPO must have written agreements with:

1. All transplant hospitals within its Donation Service Area (DSA) to coordinate its procurement activities, according to the Code of Federal Regulations.
2. Donor hospitals that include arrangements for the identification, referral, and maintenance of potential organ donors. This includes preservation and transportation of donated organs to transplant hospitals in its DSA.

These agreements must be available to the OPTN Contractor on request.

### **B. Laboratory Testing Services**

Each OPO must have written agreements with:

1. At least one Clinical Laboratory Improvement Amendment (CLIA) certified laboratory that meets OPTN standards to provide donor screening for transmissible disease, including Human Immunodeficiency Virus (HIV).
2. An OPTN approved histocompatibility laboratory to perform the necessary tissue typing of donated organs.

### **C. Tissue Bank Services**

Each OPO must have written agreements with tissue banks for efficient and effective referral, recovery, processing, preservation, storage, and distribution of tissue from donors.

### **D. Education Plans**

Each OPO must submit written summaries of education plans that include:

1. Activities for public education about organ donation, including how donor families, transplant candidates, and recipients will participate.
2. A plan to conduct or participate in professional education about organ and tissue procurement.

If an OPO does not submit an education plan, the membership application will be considered incomplete and not reviewed until the plan is submitted. The OPTN Board of Directors may also notify the Secretary of the HHS if an OPO does not submit an education plan.

### **E. Organ Allocation Plans**

Each OPO is responsible for equitable and efficient organ allocation within their DSAs that adheres to OPTN obligations. To meet this requirement, each OPO must have the necessary procedures and technology to communicate information to distribute organs to transplant

candidates at transplant hospitals within and beyond its service area.

Each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. An OPO must demonstrate it has policies and procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix L: Reviews and Actions*.

## **B.5 OPO Personnel**

Each OPO must have personnel who are qualified to effectively recover organs from all donors in its DSA. Each OPO must have the necessary staff to recover and distribute organs according to OPTN obligations, including an administrative director, a medical director, an organ donation coordinator, and an organ procurement specialist.

### **A. OPO Administrative Director**

Each OPO must identify an individual that serves as the administrative director. The administrative director, together with other OPO staff, is responsible for effective organ recovery and placement according to OPTN obligations.

### **B. Medical Director**

The OPO medical director must be a physician licensed in at least one of the states within the OPO's DSA. The OPO must submit the medical director's credentials to the OPTN Contractor. The medical director is responsible for the medical and clinical activities of the OPO.

### **C. Board of Directors**

Each OPO must have a board of directors or an advisory board with members selected according to the Code of Federal Regulations. The board of directors or advisory board has the authority to recommend policies that guide the donation, procurement, and equitable distribution of organs.

### **D. Changes in Key Personnel**

When the OPO learns that the administrative or medical director plans to leave, it must notify the OPTN Contractor immediately, within 30 days of departure, if possible. The OPO must also submit to the OPTN Contractor at this time the replacement's name and curriculum vitae.

### **E. Failure to Report Changes in Key OPO Personnel**

An OPO's failure to notify the OPTN Contractor of a change in the administrative or medical director will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix L: Reviews and Actions*.

The OPO must notify the MPSC if it has not filled a vacant administrative or medical director position within six months. The MPSC could then recommend that the OPTN Board of Directors notify the Secretary of HHS of the OPO's failure to fill the position.

## **B.6 Additional Requirements**

### **A. Inactive Status**

An OPO that is voluntarily inactive, declared inactive or withdraws from membership will no longer be allowed to list candidates on the waiting list or provide organs to transplant hospitals.

### **B. Tax Exemption**

Each OPO must be able to demonstrate that it has nonprofit status as an organization exempt from federal income taxation under *section 501* of the Internal Revenue Code of 1986.

### **C. Fiscal Procedures**

Each OPO must have policies and procedures to obtain payment for organs provided to transplant hospitals. These policies and procedures must be available to the OPTN Contractor on request.

### **D. Medicare Reimbursement**

Each OPO must have an agreement to be reimbursed under Medicare for the procurement and recovery of organs. If the OPO does not have current Medicare approval for reimbursement, it must have submitted an application to the appropriate Medicare agency which must be approved within 120 days of receiving membership in the OPTN.

### **E. Center for Medicare/Medicaid Services (CMS) Certification**

To maintain member status in the OPTN, each OPO must be certified by the Center for Medicare/Medicaid Services (CMS), and designated as a qualified OPO by the Secretary of HHS, during all periodic reviews. Each OPO must provide proof of certification to the OPTN Contractor on request.

### **F. Donation Service Area**

OPOs must demonstrate that a defined Donation Service Area (DSA) exists, consistent with information submitted to CMS, through the following information:

- Names of counties or parishes served, or the state if an entire state is served.
- Total population in the DSA, documented by the most recent official census as well as the latest data estimate of the U.S. Census Bureau performed between censuses, as required by CMS.
- The number and name of acute care hospitals in the DSA that have operating rooms, equipment and personnel to retrieve organs.

The OPO must inform the OPTN Contractor when any changes to its DSA are made.

### **G. Patient Confidentiality**

Each OPO must have documented policies and procedures in place for ensuring the confidentiality of all organ donors. These policies and procedures must be available to the OPTN Contractor on request.

## **H. Donation after Circulatory Death (DCD) Protocols**

Each OPO must develop and comply with protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the requirements as described in *Policy 2.16: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*. These protocols must be made available to the OPTN Contractor on request.

## **Appendix C: Membership Requirements for Histocompatibility Laboratories**

### **C.1 Histocompatibility Laboratory Compliance**

Each histocompatibility laboratory member must comply with all OPTN Obligations according to *Article 1.1.E: Member Compliance* and *both* of the following:

1. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR § 493.1278, unless exempt
2. The requirements, as they apply to solid organ and islet transplantation, of the American Society for Histocompatibility and Immunogenetics (ASHI) 2013 Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of April 21, 2014. This requirement does not mandate membership in either ASHI or CAP.

If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory must notify the OPTN Contractor in writing within 10 business days. The histocompatibility laboratory must also provide all documents relating to the final adverse action to the OPTN Contractor.

### **C.2 Facilities and Resources**

Histocompatibility laboratories must have considerable facilities, equipment, and resources to ensure accurate, reliable and efficient testing.

#### **A. Facilities**

The laboratory must have:

1. Enough space and equipment so that procedures and tests can be performed accurately and efficiently.
2. Adequate facilities to store medical and test records for candidates, recipients, and donors.

#### **B. Records Access**

Records for active candidates must be immediately accessible onsite. Records for recipients and donors must be accessible as necessary to meet the clinical practice needs of any associated transplant hospital or OPO.

#### **C. Transplant Program Affiliation**

Histocompatibility laboratories must have written agreements with every transplant program the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and transplant programs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.

3. A process for requesting extended HLA typing.
4. A process for reporting and verifying HLA and unacceptable antigen data at the time of registration on the waiting list and any time there are changes.
5. A process for reporting HLA typing results to the OPTN Contractor.
6. A process for resolving HLA typing discrepancies and errors.
7. The maximum turnaround time from receipt of sample to reporting of results to the transplant program.
8. A process to obtain sensitization history for each patient.
9. The frequency of periodic sample collection.
10. The frequency of antibody screenings.
11. The criteria for crossmatching.
12. The assay format that will be used for antibody screening and for crossmatching.
13. The criteria for determining unacceptable antigens used during organ allocation.
14. The duration for which specimens need to be stored for repeat or future testing.
15. If desensitization is performed, then a protocol for monitoring antibody levels.
16. If the laboratory registers candidates for the transplant program, then a process for blood type verification according to *Policy 3.3: Candidate Blood Type Determination before Waiting List Registration*.
17. If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.

#### **D. OPO Affiliation**

Histocompatibility laboratories must have written agreements with every OPO member the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and OPOs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.
3. A process for requesting extended HLA typing.
4. A process for verifying and reporting HLA typing results to the OPTN Contractor.
5. A process for resolving HLA typing discrepancies and errors.
6. The maximum turnaround time from receipt of donor sample to reporting of results to the OPO.
7. A process for prioritizing donors for histocompatibility testing.
8. The length of time for which donor specimens are required to be stored for repeat or future testing.
9. If the OPO performs crossmatching, then all methods used for crossmatching and the interpretation and reporting of the results.

### **C.3 Histocompatibility Laboratory Key Personnel**

The laboratory must employ a histocompatibility laboratory director, a technical supervisor, a general supervisor, and a clinical consultant. One person may fill one or more positions.

The size and training of the histocompatibility laboratory staff must be enough to carry out the volume and variety of tests required to ensure accuracy and prompt completion of tests. All personnel must be licensed or meet the standards required by federal, state and local regulations.

If the laboratory provides histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas transplants, then the laboratory must have personnel for the required histocompatibility testing available 24 hours a day, seven days a week.

### **A. Histocompatibility Laboratory Director Qualifications**

The histocompatibility laboratory director ensures that the laboratory provides high quality and comprehensive histocompatibility and immunogenetics testing.

The histocompatibility laboratory director must meet the requirements for at least *one* of the following pathways:

- Pathway 1:
  1. Have an M.D. or D.O. from an accredited institution, or equivalent degree from another country
  2. Have a license to practice medicine in the state where the laboratory is located
  3. Be certified in anatomic and clinical or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications of those equivalent to those required for such certification
  4. Have at least two years full-time experience directing or supervising clinical histocompatibility testing for solid organ transplantation
  
- Pathway 2:
  1. Have a doctoral degree in a medical, chemical, physical, biological, or clinical laboratory science from an accredited institution, or equivalent degree from another country
  2. Have at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics, and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation
  3. Certification as a Diplomate by the American Board of Histocompatibility and Immunogenetics, a high complexity laboratory director by the American Board of Bioanalysis, or a Diplomate by the American Board of Medical Laboratory Immunology. A professional who holds an earned doctoral degree but who does not hold one of these certifications may qualify if they were serving as director of an accredited laboratory performing human histocompatibility and immunogenetics testing before February 24, 2003

The MPSC will review, in consultation with the histocompatibility accrediting agencies, the credentials of professionals with foreign education or training and determine whether the foreign education or training is equivalent to that obtained in the United States.

Any professional being considered for the position of histocompatibility laboratory director who has not served in the role of laboratory director prior to the date of application must also provide *all* of the following:

- A portfolio of 50 cases, covered during the five years prior to the date of application that demonstrates the professional's analytical skills, ability to recognize and resolve testing and interpretation issues, and instances when the applicant made recommendations for additional testing or clinical care.
- Proof of active interaction with transplant professionals.

- A letter from the applicant that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.
- A current curriculum vitae or resume.
- Demonstrated participation in transplant or clinical laboratory professional conferences or publications in peer-reviewed journals.

All documentation that verifies training and experience must be sent directly to the OPTN Contractor from all directors of histocompatibility laboratories where the training was obtained.

## **B. Technical Supervisor Qualifications**

The technical supervisor must meet all the qualifications and fulfill the responsibilities for laboratory director according to *C.3.A. Histocompatibility Laboratory Director Qualifications* above and for technical supervisor according to *42 CFR 493*.

## **C. General Supervisor Qualifications**

A general supervisor must meet the qualifications for a general supervisor according to *42 CFR 493* and have at least three years of experience in human histocompatibility or transplant immunology testing under the supervision of a qualified histocompatibility laboratory director or technical supervisor.

## **D. Histocompatibility Technologist Qualifications**

A histocompatibility technologist must meet the qualifications for a histocompatibility technologist according to *42 CFR 493* and must have had one year of supervised experience in human histocompatibility or transplantation immunology testing, regardless of academic degree or other training and experience.

## **E. Clinical Consultant Qualifications**

The clinical consultant must meet all the qualifications for laboratory director as outlined in *C.3.A. Histocompatibility Laboratory Director Qualifications* above and for clinical consultant according to *42 CFR 493*.

## **F. Competency Testing and Continuing Education of Staff**

The laboratory must test its staff for competency in performing test procedures. The testing must be done annually, and must be completed for each type of test the staff performs.

The director, technical supervisor, and all technical staff must participate in continuing education in histocompatibility, immunogenetics or clinical transplantation as required for accreditation by national, state, and local regulatory agencies.

## **C.4 Laboratory Coverage Plan**

The histocompatibility laboratory director, in conjunction with the technical supervisor, general supervisor, and clinical consultant, must submit a detailed Laboratory Coverage Plan to the OPTN Contractor. The Laboratory Coverage Plan must describe how continuous coverage is provided by laboratory personnel.

The Laboratory Coverage Plan must address *all* of the following:

1. The laboratory must document that qualified key personnel are providing coverage at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.
2. The laboratory must document that the laboratory director, technical supervisor, general supervisor, and clinical consultant are available to provide onsite, telephone, or electronic consultation to facilitate organ acceptance and transplantation.
3. The laboratory must document if any of the responsibilities designated to the laboratory director, technical supervisor, or clinical consultant will be performed by other laboratory staff. This documentation must include a list of the duties delegated, the times when the duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure the duties are correctly performed.
4. If the laboratory is engaged in histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas donor transplants, then the laboratory must document that key personnel and qualified testing personnel are available 24 hours a day, 7 days a week to provide laboratory coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.
5. If any key personnel serves more than one histocompatibility laboratory, then the Laboratory Coverage Plan must specify how continuous coverage will be provided at each histocompatibility laboratory served.

## **C.5 Changes in Key Laboratory Personnel**

### **A. Change in Laboratory Director, Technical Supervisor, General Supervisor, or Clinical Consultant**

When the histocompatibility laboratory is informed that the laboratory director, technical supervisor, general supervisor, or clinical consultant plans to leave or otherwise ends active participation in the laboratory, the laboratory must:

1. Notify the OPTN Contractor in writing within seven business days of when the laboratory becomes aware of the change in key personnel.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment or change in status. The Personnel Change Application must document that the new or acting laboratory director, technical supervisor, general supervisor, and clinical consultant meet the requirements of these Bylaws.
3. Submit an updated Laboratory Coverage Plan no less than 30 days before the date of departure that specifies how continuous coverage will be provided at the laboratory by all key personnel during and after the transition period to a new or acting laboratory director, technical supervisor, or clinical consultant.
4. If the histocompatibility laboratory receives less than 60 days notice of the key personnel change, then the laboratory must submit a completed Personnel Change Application and updated Laboratory Coverage Plan to the OPTN Contractor within 30 days of the date of departure.

A change in key personnel can be any of the following:

1. Departure of the director, technical supervisor, general supervisor, or clinical consultant.
2. Any key personnel unavailable to perform responsibilities for more than 30 days.
3. Reinstatement of the previously designated laboratory director, technical supervisor, general supervisor, or clinical consultant.
4. Any key personnel that accepts additional responsibilities for more than 30 days at another histocompatibility laboratory.

## **B. Failure to Notify the OPTN Contractor of Key Personnel Changes**

A histocompatibility laboratory's failure to inform the OPTN Contractor of a change in the laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the required Personnel Change Application within the periods specified will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix L: Reviews and Actions*.

## **C. Rejected Key Personnel Change Applications**

The MPSC must offer the applicant an interview if the MPSC rejects a Key Personnel Change application. The applicant may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors. Any interviews, hearings, or Board of Directors appearances that occur as part of the Key Personnel Change application process will be conducted according to *Appendix L: Reviews and Actions*.

## **C.6 Histocompatibility Laboratory Policies and Procedures**

### **A. Criteria for Mandatory Performance Review a Histocompatibility Laboratory**

The OPTN Contractor may review a histocompatibility laboratory if at any time it has *any* of the following performance indicators:

- Failure to comply with the requirements and regulations according to *Section C.1: Histocompatibility Laboratory Compliance* of these Bylaws.
- Any of the following performance indicators on external proficiency testing:
  1. Less than 100% satisfactory performance in an ABO external proficiency testing program.
  2. For programs other than ABO, a less than 80% satisfactory performance on more than one external histocompatibility proficiency testing program within the previous twelve months.
- Accreditation revoked by any OPTN approved histocompatibility regulatory agency.
- A focused re-inspection by any OPTN approved histocompatibility regulatory agency.
- Restrictions imposed on the laboratory by any OPTN approved histocompatibility regulatory agency.
- One or more HLA typing or reporting errors on a deceased or living donor that results or could result in an incompatible transplant or the re-allocation of an organ to someone other than the intended recipient.
- Unresolved or repeat deficiencies identified during inspections conducted by OPTN approved regulatory agencies that are in violation of OPTN Contractor standards. When deficiencies are cited, laboratories must document that the deficiencies have been corrected.

- Complaints from transplant programs, OPOs, or other clients that have not been documented, investigated and resolved.
- Incomplete submission of all OPTN Contractor forms or forms not submitted within the 180 day time limit.

## **B. Information Required from Laboratories with Unsatisfactory Performance**

The OPTN Contractor may request at any time from a histocompatibility laboratory with unsatisfactory performance *any* of the following:

- Letters from the affiliated transplant program or OPO staff describing the level of interaction and involvement of the director, technical supervisor and clinical consultant.
- Interviews with transplant program or OPO staff.
- Laboratory complaint log and documentation of resolutions from other healthcare professionals.
- Samples of laboratory reports that demonstrate the review of patient history, notation of unusual results, and recommendations for additional testing.
- Documentation of any professional extracurricular commitments, including estimates of time required, for laboratory director, technical supervisor, general supervisor, and clinical consultant outside of the histocompatibility laboratory.
- Quality Assessment and Performance Improvement records.
- Other material as requested.

## **C. Inactive Status**

A histocompatibility laboratory that is voluntarily inactive, declared inactive or withdraws from membership will be ineligible and may not provide histocompatibility testing to any OPTN members.

### **C.7 Histocompatibility Laboratory Testing Requirements**

#### **A. Subcontracting**

If a histocompatibility laboratory refers testing to another laboratory, the subcontracting laboratory must be *both*:

1. CLIA certified or unless exempt under federal law.
2. OPTN-approved.

The laboratory director must review and approve all test results returned from the subcontracting laboratory before release. The identity of the subcontracting laboratory and that portion of the testing for which it bears responsibility must be noted in the report of the histocompatibility laboratory. A copy of the testing laboratory's report must be kept on file by the laboratory receiving the results.

**B. Submission Requirements for New Laboratories**

If a laboratory seeking OPTN membership has not previously been approved as an OPTN histocompatibility laboratory member, then the laboratory must submit procedures and test validation data for all categories and methods of testing performed to the OPTN Contractor upon request.

## **Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs**

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

The following provisions of Appendix D do not apply to VCA transplant programs:

- *D.5: Transplant Program Director*
- *D.6: Transplant Program Key Personnel*
- *D.7: Changes in Key Transplant Program Personnel*

### **D.1 Transplant Hospital Compliance**

By accepting membership in the OPTN, transplant hospitals agree to comply with all OPTN Obligations according to *Article 1.1.E: Member Compliance*.

If any regulatory agency takes a final adverse action against a transplant hospital, the transplant hospital must notify the OPTN Contractor in writing within 10 business days. The transplant hospital must also provide all documents relating to the final adverse action to the OPTN Contractor.

### **D.2 Designated Transplant Program Requirement**

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HSS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program for at least one of the organ types involved in multi-visceral transplant. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

### **D.3 Quality Assessment and Performance Improvement (QAPI) Requirement**

- A. Transplant hospitals must develop, implement and maintain an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives. The QAPI plan must incorporate all designated transplant programs at the transplant hospital.
- B. The hospital must document implementation of all elements of the QAPI plan.

### **D.4 Facilities and Resources**

A successful transplant program requires adequate facilities and resources. The sections that follow describe the required facilities and resources.

#### **A. Facilities**

Transplant hospitals must allocate sufficient operating and recovery room resources, intensive care resources, surgical beds, and personnel to the transplant program.

#### **B. OPO Affiliation**

The transplant program must have letters of agreement or contracts with an OPO member as defined in *Article 1.3 OPO Members* of these Bylaws.

#### **C. Histocompatibility Laboratory Affiliation**

A transplant program must have a written agreement with an OPTN approved histocompatibility laboratory to perform the tissue typing of recipients and donors. The histocompatibility laboratory must meet the standards for testing as described in *Appendix C: Membership Requirements for Histocompatibility Laboratories* of these Bylaws.

#### **D. Blood Bank Services**

Transplant programs must have access to large quantities of blood and provide proof of extensive blood bank support.

#### **E. Additional Laboratory Services**

The matching of transplant recipients and donors, as well as routine evaluation and follow-up of transplant patients requires sophisticated laboratory facilities. Transplant programs must have immediate access to microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as the necessary resources to monitor immunosuppressive medications.

### **D.5 Transplant Program Director**

Each transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program director, along with the primary surgeon and physician, has the responsibility to submit a detailed Program Coverage Plan (PCP) to the OPTN Contactor that describes how continuous medical and surgical coverage is provided by transplant surgeons and physicians. See *D.6.B. Surgeon and*

*Physician Coverage (Program Coverage Plan)* in this appendix for more information on the Program Coverage Plan.

## **D.6 Transplant Program Key Personnel**

Designated transplant programs must have certain key personnel on site. These key personnel include a qualified primary surgeon and primary physician that meet the requirements set forth in these Bylaws. For the detailed primary surgeon and primary physician requirements for specific organs, see the following appendices of these Bylaws:

- *Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs*
- *Appendix F: Membership and Personnel Requirements for Liver Transplant Programs*
- *Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs*
- *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*

### **A. Primary Transplant Surgeon and Physician**

The primary surgeon and primary physician are responsible for ensuring the operation and compliance of the program according to the requirements set forth in these Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements. The individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

A transplant hospital applying as a new member or for a key personnel change must include for the proposed primary surgeon or physician a report from the hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification, and training and confirm that they are currently a member in good standing.

As part of the plan for continuing policy compliance that is required in the membership application, each primary surgeon or primary physician will submit an assessment of all physicians and surgeons in the program. This assessment must include any involvement in prior transgressions of OPTN obligations and plans to ensure compliance. This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application and to the satisfaction of the Membership and Professional Standards Committee (MPSC).

### **B. Surgeon and Physician Coverage (Program Coverage Plan)**

The program director, in conjunction with the primary surgeon and primary physician, must submit a detailed Program Coverage Plan to the OPTN Contractor. The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program.

A transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

The Program Coverage Plan must address *all* the following requirements:

1. Transplant programs must have transplant surgeons and transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.
2. Transplant programs must provide patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.
3. A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation.
4. A transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved by the MPSC.
5. Unless the MPSC provides an exemption for specific reasons, the primary surgeon or primary physician cannot be designated as the primary surgeon or primary physician at more than 1 transplant hospital unless there are additional transplant surgeons or transplant physicians at each of those facilities.
6. Additional Transplant Surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.
7. Additional Transplant Physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

### **C. Surgeons and Physicians Designated as Primary Transplant Surgeon or Physician before July 1, 2006**

Designated transplant programs whose current primary surgeon or physician received approval to serve in the primary role for the program prior to July 1, 2006 will continue to be qualified as long as the same surgeon or physician continues to serve the program in the primary role. If the primary surgeon or physician ends their involvement with the transplant program, the program must have an individual on site who meets the primary transplant surgeon or physician requirements, as described in *Appendices E through J* of these Bylaws, which are in effect at the time that the individual is proposed as the primary surgeon or physician.

Anyone serving as the primary transplant surgeon or physician for a designated transplant program only holds that designation until they cease to serve in the primary role for that transplant program. This designation is not transferrable to other programs or hospitals.

A primary transplant surgeon or physician must meet the primary transplant surgeon or physician requirements that are in effect at the time that the surgeon or physician is proposed as primary surgeon or physician.

### **D.7 Changes in Key Transplant Program Personnel**

Designated transplant programs must have key personnel, specifically a primary surgeon and a primary physician, who meet the required minimum levels of commitment to and knowledge of organ procurement

and transplantation as specified in these Bylaws. All transplant programs should develop a succession plan that addresses changes in these key personnel.

When a designated transplant program is informed of a change in key personnel, it must notify the OPTN Contractor within seven business days in writing and follow the procedures that are described below. A change in key personnel can be *any* of the following:

- Departure of the primary surgeon or primary physician.
- Change in position from primary surgeon or primary physician to an additional surgeon or physician.
- Temporary leave.
- Reinstatement of the previously designated primary surgeon or physician.

Transplant programs are also responsible for maintaining Program Coverage Plans as described in *Section D.6.B. Surgeon and Physician Coverage (Program Coverage Plan)* above during changes in key personnel. The Program Coverage Plan must address instances when key personnel are unavailable to perform their transplant duties for short periods of time.

#### **A. Primary Surgeon or Primary Physician Departure**

When the transplant hospital is informed that either the primary surgeon or primary physician plans to leave the hospital or otherwise end their active participation in the transplant program, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment. The Personnel Change Application must document that the new primary surgeon or primary physician meets the requirements of these Bylaws.

If the transplant hospital receives less than 60 days advance notice of the key personnel change, then the transplant hospital must submit a completed Personnel Change Application to the OPTN Contractor within 30 days from the date the OPTN Contractor was notified.

If a program is unable to demonstrate through a completed Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary surgeon and primary physician, the transplant hospital must *either*:

- Inactivate the designated transplant program.
- Withdraw its designated transplant program status as described in *Section K.4: Withdrawal or Termination of Designated Transplant Program Status* of these Bylaws.

#### **B. Primary Surgeon or Primary Physician Change in Role**

When the transplant hospital plans to propose a new primary surgeon or primary physician and the currently designated primary surgeon or physician will remain on staff as an additional surgeon or physician, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.

2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the change will take effect. The Personnel Change Application must document that the new primary surgeon or physician meets the requirements of these Bylaws.

The transition to the new primary surgeon or primary physician is effective after the application has been reviewed and approved by the MPSC or an Ad hoc Subcommittee of the MPSC, as described in *Appendix A: Membership Application and Review* of these Bylaws.

### **C. Primary Surgeon or Primary Physician Temporary Leave**

If the primary surgeon or physician must take a temporary leave of absence or otherwise temporarily cease their active participation with the transplant program, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the individual's leave begins. The Personnel Change Application must document that the replacement primary surgeon or physician meets the requirements of these Bylaws.

Temporary leave is defined in these Bylaws as greater than 30 days but less than one year.

If the transplant hospital receives less than 60 days advance notice of the leave, then the transplant hospital must submit a complete Personnel Change Application to the OPTN Contractor within 30 days from the date the OPTN Contractor was notified.

If a program is unable to demonstrate through a completed Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary surgeon and physician, the transplant hospital must *either*:

- Inactivate the designated transplant program.
- Withdraw its designated transplant program status as described in *Appendix K*: of these Bylaws.

### **D. Reinstatement of Previously Designated Primary Surgeon or Primary Physician**

If the previously designated primary surgeon or primary physician returns to the same transplant program within one year of departure the individual can be considered for reinstatement as the primary surgeon or primary physician. The transplant hospital must submit a written reinstatement request to the OPTN Contractor.

The written reinstatement request must include *all* of the following:

1. A letter from the Transplant program director, department chair, or chief of the division, verifying the individual's current working knowledge and experience.
2. A letter from the individual confirming the individual's on-site availability and commitment to the program.

3. A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume as primary surgeon or primary physician.

The MPSC or an Ad hoc Subcommittee of the MPSC will review requests for reinstatement, as described below. In cases where reinstatement of a surgeon or physician affects the transplant program's current status, the MPSC will recommend the appropriate new program status, along with any resulting special conditions.

#### **E. Failure to Notify the OPTN Contractor of Key Personnel Changes**

A member's failure to notify the OPTN of a primary surgeon or physician change or to submit the required Personnel Change Application within the periods specified will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix L: Reviews and Actions*.

#### **F. Processing Applications for Changes to Key Personnel**

When processing applications to change key personnel, the MPSC Chair is authorized to appoint an Ad hoc Subcommittee of at least two Committee members, other than the MPSC chair. This Ad hoc Subcommittee will review the credentials of the proposed new key personnel.

The Subcommittee may grant, with agreement of the MPSC Chair, interim approval effective until review by the entire MPSC at its next meeting. Interim approval will not extend beyond the next meeting of the entire MPSC and will automatically expire if the entire MPSC does not approve the interim approval.

Designated transplant programs must have qualified key personnel for the program at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.

The MPSC must offer the member an interview if the MPSC rejects a Key Personnel Change application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors. Any interviews, hearings, or Board of Directors appearances that occur as part of the Key Personnel Change application process will be conducted according to *Appendix L: Reviews and Actions*.

### **D.8 Other Transplant Program Personnel**

Transplant programs must have other support personnel on staff to ensure quality patient care. The sections below provide details of support staff that a transplant program is required to have on staff.

#### **A. Clinical Transplant Coordinator**

Each transplant program will have on staff at least one Clinical Transplant Coordinator. The Clinical Transplant Coordinator will be a designated member of the transplant team, working with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation.

The Clinical Transplant Coordinator will work with patients to ensure continuity of care. The Coordinator will work with members of the transplant team, including physicians, surgeons, nurses, social workers, financial coordinators and administrative personnel at the transplant program.

The Coordinator should be a registered nurse or other licensed clinician who oversees a team of other healthcare personnel and support staff. Responsibilities will include, but are not limited to:

- Assuring that the necessary preliminary tests are completed.
- Participating in candidate and family education.
- Assisting in the evaluation and selection of potential living donors.
- Monitoring the candidate's status while on the organ transplant waiting list.
- Educating staff nurses on transplantation.
- Acting as the transplantation resource person for all staff nurses.
- Acting as liaison between patients' families and other health care team members.
- Preparing patients for discharge and outpatient follow-up care.
- Monitoring and following all diagnostic tests.
- Communicating all patient issues and concerns to appropriate transplant physicians.
- Coordinating comprehensive care with other team members, including the financial coordinator, social worker, dietician, and others.
- Participating in the organ procurement process by taking organ offer calls, dispatching the organ procurement team, and arranging for potential organ recipients to be admitted to the hospital.

Additional responsibilities may include clinical research studies, public and professional education, and submission of data required by the OPTN.

## **B. Financial Coordinator**

Each transplant hospital should have on staff a Financial Coordinator who will be responsible for coordinating and clarifying the available financial resources for patient care. The Financial Coordinator will be a designated member of the transplant team, working with patients and their families to coordinate the financial resources required for care, beginning with the transplantation evaluation and continuing after transplantation to ensure continuity of care.

The Coordinator will also work with other members of the transplant team, insurers and administrative personnel at the transplant hospital. Responsibilities include, but are not limited, to:

- Obtaining detailed patient insurance benefit information for all phases of the transplant process.
- Discussing benefits and other transplant financial issues with patients or family members during the initial evaluation.
- Advising patients on insurance and billing issues and options.
- Serving as a resource for patients and their family members on financial matters.
- Verifying transplant coverage and other medical benefits and acquiring the necessary referrals and authorizations.
- Monitoring and updating information regarding insurance data, physicians, authorizations, and preferred providers.

- Assisting patients with questions concerning insurance and other financial issues.
- Identifying and effectively communicating financial information to transplant team members, patients and their families with an emphasis on identifying potential patient out-of-pocket expenses.
- Working with patients, their families and team members when possible to help address insurance coverage gaps and to help find alternative funding options.
- Facilitating resolution of patient billing issues.

### **C. Clinical Transplant Pharmacist**

Each transplant program should identify at least one Clinical Transplant Pharmacist on staff who will provide pharmaceutical expertise to transplant recipients. The Clinical Transplant Pharmacist should be a member of the transplant team, providing comprehensive pharmaceutical care to transplant recipients.

The Transplant Pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel. The Transplant Pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy.

### **D. Medical Expert Support**

The proper care and management of transplant recipients require both physicians and ancillary health professionals. The transplant program must show proof of collaboration with experts in these fields:

- Anesthesiology
- Hepatology
- Histocompatibility and immunogenetics
- Immunology
- Infectious disease
- Nephrology, including dialysis capability
- Pathology
- Pediatrics
- Physical therapy and rehabilitation medicine
- Pulmonary medicine, including respiratory therapy support
- Radiology

### **E. Mental Health and Social Support**

Each transplant program must have on staff professionals who are designated members of the transplant team and whose primary responsibility is coordinating the psychosocial needs of transplant candidates, recipients, living donors, and their families. These professionals will work with patients and families in a compassionate, culturally sensitive, and thoughtful way to facilitate continuity of care.

Responsibilities will include, but are not limited to:

- The psychosocial evaluation of potential living donors and recipients.
- Substance abuse evaluation, treatment, referral, and monitoring.
- Individual counseling.
- Crisis intervention.
- Support groups and newsletters.
- Patient care conferences.
- Patient advocacy
- Patient and family education.
- Referral to community services such as vocational rehabilitation and housing.
- Death, dying, and bereavement counseling.
- Transplant team building.
- Department meetings, including staff and process improvement meetings.
- Participation in organ donation awareness initiatives.
- Participation with community advocacy groups such as the National Kidney Foundation and the Coalition for Donation.

## D.9 Investigation of Transplant Personnel

The transplant hospital must investigate any personnel on staff at a designated transplant program if directed to do so by the MPSC. The MPSC will request an investigation to examine an individual's role in a matter reviewed or currently under review by the MPSC, and explain the reason for the investigation request to the transplant hospital. The transplant hospital must inform the MPSC when it has started the investigation and when it completes the investigation. The transplant hospital must also provide documentation that it conducted the investigation according to the requirements of these Bylaws.

The hospital's investigation must use the hospital's standard medical peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process.

A member's failure to investigate designated transplant program staff as directed will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix L: Reviews and Actions*.

## D.10 Review of Transplant Program Functional Activity

### A. Functional Inactivity

Each transplant program must remain functionally active by performing a minimum number of transplants. For purposes of these Bylaws, functional inactivity is defined according to Table D-1 below:

**Table D-1: Functional Inactivity**

For this transplant program type:	Functional inactivity is defined as:
Kidney, Liver, or Heart	Failure to perform at least 1 transplant in 3 consecutive months
Lung	Failure to perform at least 1 transplant in 6 consecutive months

For this transplant program type:	Functional inactivity is defined as:
Stand-alone pediatric	Failure to perform at least 1 transplant in 12 consecutive months
Pancreas	<p><i>Both</i> of the following:</p> <ol style="list-style-type: none"> <li>1. Failure to perform at least 2 transplants in 12 consecutive months</li> <li>2. <i>Either</i> of the following in 12 consecutive months:                             <ul style="list-style-type: none"> <li>• A median waiting time of the program’s kidney-pancreas and pancreas candidates that is above the 67<sup>th</sup> percentile of the national waiting time</li> <li>• The program had no kidney-pancreas or pancreas candidates registered at the program</li> </ul> </li> </ol>
Islet, intestinal, and VCA	No functional inactivity definitions have been established

**B. Notification Requirements for Transplant Program Functional Inactivity**

If a transplant program is notified by the MPSC that the program has been identified as functionally inactive, the transplant program must provide written notice to *all* of the following:

1. Potential candidates
2. All candidates registered on the waiting list

For all transplant programs except pancreas programs, written notice must be provided within 30 days of the date of the MPSC notification to the program and must include *all* of the following:

1. The dates identified in the MPSC notification during which no transplants were performed.
2. The reason no transplants were performed.
3. The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital.
4. A copy of the OPTN Contractor’s Patient Information Letter.

For pancreas programs, written notice must be provided within 30 days of the date of the MPSC notification to the program and must include *all* of the following:

1. The dates identified in the MPSC notification during which fewer than 2 transplants were performed.
2. The reason fewer than 2 transplants were performed.
3. The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital.
4. A copy of the OPTN Contractor’s Patient Information Letter.
5. The names and contact information of all pancreas programs within the same state or commonwealth and all pancreas programs within 125 nautical miles of the functionally inactive program regardless of state or commonwealth boundaries.
6. The following information:

- a. For potential candidates and candidates on the waiting list, the program's median waiting time in the consecutive 12 month period for kidney-pancreas and pancreas candidates compared to the 67<sup>th</sup> percentile of the national waiting time.
- b. For potential candidates, that the program had no kidney-pancreas or pancreas candidates on the waiting list in the consecutive 12 month period.

### **C. Review of Member Functional Inactivity**

Transplant program functional inactivity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC.

As part of its review of a program's functional inactivity, the MPSC may require, that the member participate in an informal discussion. The informal discussion will be conducted according to *Appendix L: Reviews and Actions*.

The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program's functional inactivity. The MPSC must offer the member an informal discussion before recommending that the program inactivate or withdraw its designated transplant program status. A program's failure to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix L: Reviews and Actions*.

## **D.11 Additional Transplant Program Requirements**

### **A. Transplant Program Performance**

*Appendix D.12.A* does not apply to VCA transplants.

The MPSC will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.

For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:

1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

The MPSC review will be to determine if the higher hazard ratio or events can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program, the program, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix L: Reviews and Actions*.

As part of this process, the MPSC may conduct a peer visit to the program at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to *Appendix L: Reviews and Actions*.

The MPSC may recommend that a member inactivate a program, or a component of a program, or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. The MPSC must offer the member an informal discussion before recommending that the program inactivate or withdraw its designated transplant program status. A program's failure to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix L: Reviews and Actions*.

**B. Patient Notification Requirements for Waiting List Inactivation**

A transplant program must provide written notice to candidates if it does *either or both* of the following:

1. Inactivates its waiting list for 15 or more consecutive days.
2. Inactivates its waiting list for 28 or more cumulative days during any calendar year.

A transplant program must provide written notice *each* time it reaches either of the inactive waiting list thresholds listed above. Written notice must include *all* of the following:

1. The reason for the inactivity
2. The expected length of time that the waiting list will be inactive
3. The explanation that during the period of inactivity, organs cannot be accepted on the candidate's behalf at this transplant program
4. The options available to the candidate during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
5. How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
6. A copy of the OPTN Contractor's Patient Information Letter

**Note:** If written notice is required because a transplant program exceeded the inactive waiting list threshold due to *cumulative* periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation.

Written notice must be provided within the periods defined in the table below:

<b>For...</b>	<b>Written Notice Must be Provided...</b>
Periods of waiting list inactivation scheduled at least 30 days in advance	30 days before inactivity begins.
Periods of waiting list inactivation scheduled less than 30 days in advance	No more than 7 days following the initial date of waiting list inactivation.

For...	Written Notice Must be Provided...
Any periods of waiting list inactivation related to a cumulative period of inactivation	No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.

**C. Routine Referral Procedures**

Each transplant hospital must develop and follow routine referral procedures for all potential donors. Each transplant hospital is further expected to demonstrate compliance based on an annual medical record review, performed in collaboration with the OPO. Any program found to be out of compliance will be reviewed by the MPSC.

**D. Candidate Selection Procedures**

Each transplant program must establish procedures for selecting transplant candidates and distributing organs efficiently and equitably.

**E. Donation after Circulatory Death (DCD) Protocols**

Each transplant hospital must develop and comply with protocols to facilitate the recovery of organs from DCD donors. Transplant hospital DCD recovery protocols must address the requirements as described in Policy 2.13: *Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*.

**F. Veteran’s Administration (VA) Dean’s Committee Hospitals**

VA Hospitals that are Dean's Committee Hospitals and share a common university based transplant team, do not need to submit a separate membership application to the OPTN Contractor, but may be considered members under the university program with which they are affiliated.

Independent VA Hospitals, or VA Hospitals that are not Dean's Committee Hospitals sharing a common university based transplant team, must submit an application and be approved for OPTN membership in order to receive organs for transplantation.

**G. Relocation or Transfer of Designated Transplant Programs**

A designated transplant program may be transferred from one OPTN member transplant hospital to another hospital within the same metropolitan area if the following requirements are met:

1. Both OPTN member transplant hospitals voluntarily consent in writing to the transfer of designated program status and to the transfer of one or more transplant programs from the original facility to the new hospital.
2. The Transplant Surgeon, Transplant physician, immunology, tissue typing and organ procurement services associated with the original transplant hospital must be available to the new hospital by using most of the same personnel that have been performing these services in the original hospital.

3. The original transplant hospital voluntarily agrees in writing to inactive status for those transplant programs being relocated from the original facility for at least three months and to relinquish its designated status for those programs being relocated until it has attained designated status based solely upon transplants performed at the original facility after the transfer.
4. Programs that have conditionally approval may be transferred to the new hospital along with the designated program, provided that the conditionally approved program requirements in effect at the time of transfer are met.
5. The new hospital must meet the requirements for OPTN transplant hospital member.

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

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated kidney transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated kidney transplant program.
- Performing living donor kidney recoveries and transplants, if applicable.

All transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

### **E.1 Program Director, Primary Transplant Surgeon and Primary Transplant Physician**

A kidney transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Appendix D, Section D.6.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### **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. In the case of a surgeon who has just completed training and whose American Board of Urology certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month 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. The surgeon must have completed at least one of the 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 formal 2-year surgical 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 the

- surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant. 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 the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
  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 American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized surgical fellowship training program accepted by the OPTN Contractor as described in the *Section E.4: Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows.
  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, co-surgeon, or first assistant at a designated kidney transplant program. Of these 45 kidney transplants, 23 or more must have been performed as primary surgeon or co-surgeon. 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, co-surgeon, or first assistant. Of these 15 kidney procurements, at least 8 must have been performed as primary surgeon or co-surgeon. 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 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.

### **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 and Actions* of these Bylaws.

### **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.

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. The primary transplant physician must have completed at least one of the pathways listed below:
  - a. The transplant nephrology fellowship pathway, as described in *Section E.3.A. 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. Transplant Nephrology Fellowship Pathway**

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

1. The physician completed at least 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 50 or more transplants each year. The training must have included at least 6 months of clinical inpatient 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 kidney recipients and continued the outpatient follow-up of these recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship was longer than 12 months, the physician also must have been directly involved in the outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive months. 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.
3. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.
  4. During the fellowship period, the physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program's primary transplant physician.
  5. 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.
  6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  7. 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.
  8. 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 the outpatient follow-up of 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 transplant program. 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 was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
3. The physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
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 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.
5. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
7. 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. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, 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.
2. 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.
3. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is 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 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.
5. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation,

- donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
  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 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 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 for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, 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. During the four years that include the physician's three-year pediatric nephrology fellowship and twelve-month pediatric transplant nephrology fellowship, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.
5. 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.
6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  7. 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.
  8. 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 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 for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, 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 was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
  5. 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.
  6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  7. 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.
  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 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.

## **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 and Actions* of these Bylaws.

## **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 been involved in the primary care of 23 or more newly transplanted kidney recipients, and has continued the outpatient follow-up of 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.
2. The physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
3. The physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by

- the OPTN Contractor. This potential living kidney donor log must and be signed by program director, division Chief, or department Chair from the program where the physician gained this experience
4. 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.
  5. The physician has 12 months experience on an active kidney inpatient 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. These 12 months of experience must be acquired within a 2-year period.
  6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  7. 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.
  8. The program has established and documented a consulting relationship with counterparts at another kidney transplant program.
  9. 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.
  10. 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 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.

## **E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs**

### **A. Transplant Surgeon Fellowship Training Programs**

Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year surgical transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including kidneys.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 60 kidney transplants during each of the fellowship training.

### **B. Transplant Physician Fellowship Training Programs**

Physicians qualifying as primary transplant physician based on completion of a formal transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplantation Adult Transplant Nephrology Fellowship Training Program, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including kidneys.
2. The program is at a hospital that has an ACGME approved nephrology program.
3. The program performs at least 50 kidney transplants per year if the program is training one transplant nephrology fellow, and performs at least 30 additional kidney transplants per year for each additional fellow it trains.
4. The program's curriculum must include training and experience in end-stage renal disease, training in the selection of appropriate transplant recipients and donors, experience in the immediate and long term care of the transplant recipient, and training in the performance of kidney transplant biopsies. Additionally there must be an emphasis on the management of immunosuppressive agents and the evaluation of kidney transplant dysfunction.
5. The program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period. The kidney trainee must primarily manage the transplant recipient's medical care including hypertension, diabetes, and dialytic

problems. Trainees must also serve as a primary member of the transplant team and participate in making decisions about immunosuppression.

## **E.5 Kidney Transplant Programs that Perform Living Donor Recovery**

A kidney recovery hospital is a designated kidney transplant program that performs the surgery to recover kidneys from living donors for transplantation. Kidney recovery hospitals must meet all the requirements of a designated kidney transplant program as outlined above and must also have:

1. Protocols and resources in place for performing living donor evaluations.
2. Surgical resources on site for open or laparoscopic living donor kidney recoveries.

Some pediatric living donor or kidney paired donation transplants may require that the living organ donation occurs at a hospital that is separate from the approved transplant hospital.

### **A. Living Donor Medical Evaluation**

The kidney recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the living donor.

### **B. Living Donor Psychological Evaluation**

The kidney recovery hospital must have the clinical resources to perform a psychosocial evaluation of the living donor.

### **C. Independent Living Donor Advocate (ILDA)**

The kidney recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

### **D. Primary Open Living Donor Kidney Surgeon**

A kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet *one* of the following criteria:

- Completion of a formal 2-year surgical transplant fellowship in kidney at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or other recognized fellowship training program accepted by the OPTN Contractor as described in *Section E.4.A: Transplant Surgeon Fellowship Training Programs*.
- Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. At least 5 of these open nephrectomies must have been performed as the primary surgeon or co-surgeon. The open nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

### **E. Primary Laparoscopic Living Donor Kidney Surgeon**

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon, co-surgeon, or first assistant. Seven of these nephrectomies must have been performed as primary surgeon or co-surgeon, and this role should be documented by a letter from the fellowship program director, program director, division chief, or department chair from the program where the surgeon gained this experience. The laparoscopic nephrectomies must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

### **F. Kidney Paired Donation (KPD)**

Transplant hospitals that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate KPD contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

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

### **F.1 Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs**

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated liver transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated liver transplant program.
- Performing living donor liver recoveries and transplants, if applicable.

All transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

### **F.2 Liver Program Director, Primary Liver Transplant Surgeon and Primary Liver Transplant Physician**

A liver transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.6.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### **F.3 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. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month 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. The primary must have completed at least one of the 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 formal 2-year surgical 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 the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant. 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 the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
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 liver transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in *Section F.5. Approved Liver Surgeon Transplant Fellowship Programs* that follows.
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, co-surgeon, or first assistant at a designated liver transplant program. Of these 60

- liver transplants, 30 or more must have been performed as primary surgeon or co-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 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, co-surgeon, or first assistant. Of these 30 liver procurements, at least 15 must have been performed as primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of procurement 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.

### **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 and Actions* of these Bylaws.

#### **F.4 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, current board certification in transplant hepatology, or a current pediatric transplant hepatology certification of added qualification by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

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. The physician must have completed at least one of the 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 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.

### **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 must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
6. 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 designated liver 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 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 must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
5. 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 or a pediatric transplant hepatology certification or added qualification by the American Board of Pediatrics or 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 must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
6. 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.
7. 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 or a current pediatric transplant hepatology certification of added qualification by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, 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 must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
7. 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 or a current pediatric transplant hepatology certification or added qualification by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, 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 transplant 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 must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
7. 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.

#### **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 and Actions* of these Bylaws.

## **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 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.
2. 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.
3. 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. These 12 months of experience must be acquired within a 2-year period.
4. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
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.4.A through F.4.F* above at the end of the 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.

## **F.5 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
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.

### **A. Director of Liver Transplant Anesthesia Administrative Responsibilities**

The director of liver transplant anesthesia should be a designated member of the transplant team and will be responsible for establishing internal policies for anesthesiology participation in the

peri-operative care of liver transplant patients. These policies will be developed in the context of the institutional needs, transplant volume, and quality improvement initiatives.

## **B. Required Policies for Anesthesiology Participation**

The policy for anesthesiology participation must establish a clear communication channel between the transplant anesthesiology service and services from other disciplines that participate in the care of liver transplant patients. The types of activities to consider include:

- Peri-operative consults
- Participation in candidate selection
- Participation in morbidity and mortality conferences (M&M Conferences)
- Development of intra-operative guidelines based on existing and published knowledge

## **C. Director of Liver Transplant Anesthesia Clinical Responsibilities**

The director of liver transplant anesthesia has clinical responsibilities that include but are not limited to the following:

- Pre-operative assessment of transplant candidates
- Participation in candidate selection
- Intra-operative management
- Post-operative visits
- Participation on the Selection Committee
- Consultation pre-operatively with subspecialists as needed
- Participation in morbidity and mortality (M&M) conferences

## **D. Director of Liver Transplant Anesthesia Qualifications**

The director of liver transplant anesthesia should have *one* of the following:

1. Fellowship training in Critical Care Medicine, Cardiac Anesthesiology, or a Liver Transplant Fellowship, that includes the peri-operative care of at least 10 liver transplant recipients.
2. Experience in the peri-operative care of at least 20 liver transplant recipients in the operating room, within the last 5 years. Experience acquired during postgraduate residency training does not count for this purpose.

The director of Liver Transplant Anesthesia should also earn a minimum of 8 hours of credit in transplant related educational activities from the Accreditation Council for Continuing Medical Education (ACCME) Category I Continuing Medical Education (CME) within the most recent 3-year period.

## **F.6 Approved Liver Surgeon Transplant Fellowship Programs**

Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year surgical transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another

recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including livers.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 50 liver transplants during each year of the fellowship training.

## **F.7 Liver Transplant Programs that Perform Living Donor Recovery**

A liver recovery hospital is a designated liver transplant program that performs the surgery to recover livers for transplantation from living donors. Liver recovery hospitals must meet all the requirements of a designated liver transplant program as outlined above and must also have:

1. At least 2 surgeons on site who have demonstrated experience as described below.
2. Procedures and resources in place for performing living donor assessments.

### **A. Living Donor Surgeon Requirements**

A liver recovery hospital must have on site *at least* 2 surgeons who:

1. Meet the primary liver transplant surgeon requirements as outlined in *Section F.2.* above.
2. Have demonstrated experience as the primary surgeon, co-surgeon, or first assistant by completion of at least 20 major liver resection surgeries, including living donor procedures, splits, reductions, and resections, within the past 5 years. Of these 20 major liver resection surgeries, 7 must have been live donor procedures, and at least 10 must have been performed as the primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of the surgery, 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.

In the case of pediatric living donor transplantation, it may be necessary that the live organ recovery occurs at a hospital that is distinct from the approved liver transplant program.

### **B. Living Donor Medical Evaluations**

The liver recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the living donor.

### **C. Living Donor Psychosocial Evaluation**

The liver recovery hospital must have the clinical resources to perform a psychosocial evaluation of the living donor.

### **D. Independent Living Donor Advocate (ILDA)**

The liver recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.*

## **E. Conditional Program Approval Status**

If the program does not have a second surgeon on site who has performed at least 7 living donor liver recoveries within the past 5-years, the program may be eligible for conditional approval status if the surgeon:

1. Has completed the requirement for obtaining experience in 20 major liver resection surgeries as described in *Section F.6.A* above.
2. Meets all other requirements of a primary liver transplant surgeon.

The transplant program may be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option will be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at all living donor liver recoveries.

The program must comply with interim operating policies and procedures as required by the MPSC. This may include submitting reports describing the surgeon's progress towards meeting the requirements, and any other operating conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care. The program must provide a report prior to the end of the first year of conditional approval documenting that the surgeon has met or is making sufficient progress toward performing 7 living donor liver recoveries or that the program is making sufficient progress in employing a transplant surgeon who meets this as well as all other criteria for a qualified live donor liver surgeon.

Should the surgeon meet the requirements before the conditional approval period ends, the program may submit a progress report and request review by the MPSC. The program's approval status will be made available to the public.

## **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 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.8 Membership and Personnel Requirements for Intestine Transplant Programs**

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated intestine transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated intestine transplant program.

All intestine transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

## **F.9 Intestine Program Director, Primary Intestine Transplant Surgeon, and Primary Intestine Transplant Physician**

An intestine transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a surgeon or physician who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Appendix D, Section D.7.B: Surgeon and Physician Coverage* of these Bylaws.

## **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.

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.

The surgeon must have completed at least *one* of the pathways listed below:

- a. The primary intestine transplant surgeon full approval pathway, as described in *Section F.11.A* below.
- b. The primary intestine transplant surgeon conditional pathway, as described in *Section F.11.B* below.

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

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal surgical 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 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement 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 an intestinal transplant training program approved by the American Society of Transplant Surgeons or the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in *Section F.14: Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows.
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. 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. This procedure must be documented in a log that includes the date of procurement 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.

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.

The physician must have completed at least *one* of the pathways listed below:

- a. The primary intestine transplant physician full approval pathway, as described in *Section F.12.A* below.
- b. The primary intestine transplant physician conditional pathway, as described in *Section F.12.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 an intestine transplant surgeon 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 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 an 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.
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 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.
  3. 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. These 12 months of experience must be acquired within a 2-year period.
  4. 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.
  5. 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.

## **F.12 Conditional Intestine Program Approval**

Either the primary surgeon or primary physician must qualify through one of the full approval pathways described above in sections *F.11.A* or *F.12.A* for the program to be eligible for conditional approval status. If either the primary surgeon or primary physician qualify through one of the conditional pathways described above in sections *F.11.B* or *F.12.B*, the program must meet the requirements as described below to obtain full approval:

- The transplant program is granted 36 months to fully comply with all membership requirements. This option is available to new programs as well as previously approved programs that experience a change in key personnel.
- The program must comply with all policies and procedures as required by the MPSC. This includes submitting reports describing the surgeon or physician's progress towards meeting the requirements, and any other conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care.
- During this 36-month period of conditional approval, the surgeon must be present at all intestine transplant surgeries.
- During this 36-month period, the physician must be directly involved in the primary care of all intestine patients, including new recipients.

Prior to the end of each year of conditional approval, the program must provide an annual report documenting at least *one* of the following:

- The designated surgeon has met or is making sufficient progress toward performing 3 or more intestine transplants
- The designated physician has met or is making sufficient progress toward the direct involvement in the primary care of 3 or more intestine transplant patients
- The program is making sufficient progress in employing a transplant surgeon or physician who meets this, as well as all other criteria, for a primary intestinal transplant surgeon or physician

Should the surgeon or physician meet the requirements before the conditional approval period ends, the program may submit a progress report and request a review by the MPSC.

### **A. Full Approval Following Conditional Approval**

The conditional approval period begins on the first approval date granted to the application, whether it is interim approval granted by the MPSC subcommittee, the MPSC or approval granted by the full Board of Directors. The conditional approval period ends 36 months after the first approval date of the application.

The MPSC may consider on a case-by-case basis granting a 12-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete the requirements within the 36-month approval period.

Once the program has met the full approval requirements for both primary surgeon and primary physician, the program may petition the OPTN Contactor in writing for full approval.

### **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 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.

## **F.13 Approved Intestine Surgeon Transplant Fellowship Programs**

Surgeons qualifying as primary transplant surgeon based on completion of a formal transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contactor that meets *all* of the following criteria:

1. The program is at a transplant hospital that transplants two or more organs, including liver and intestines.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 10 intestine transplants during each year of the fellowship training.

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

This appendix describes the information and documentation transplant hospitals are required to provide when:

- Submitting a completed membership application for approval as a designated pancreas or pancreatic islet transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated pancreas or pancreatic islet transplant program.

It does not include the general membership requirements that all transplant programs must meet, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

### **G.1 Pancreas Program Director, Primary Transplant Surgeon and Primary Transplant Physician**

A pancreas transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.6.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### **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. In the case of a surgeon who has just completed training and whose American Board of Urology certification is pending, the Membership and Professional Standards Committee

(MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month 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. The surgeon must have completed at least one of the 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 formal 2-year surgical 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 the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the

- medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant. 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 the surgeon's fellowship operative log. The date of procurement, Donor ID, and the fellowship director's signature must be provided with this log.
  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 American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows.
  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, co-surgeon, or first assistant, at a designated pancreas transplant program. Of these 20 pancreas transplants, 10 or more must have been performed as primary surgeon or co-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 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, co-surgeon, or first assistant. Of these 10 pancreas procurements, at least 5 must have been performed as primary surgeon or co-surgeon. These procurements must be documented in a log that includes the date of procurement 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.

### **C. Alternate Pathway for Predominantly Pediatric Programs**

If a surgeon does not meet the requirements for primary pancreas 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 pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections G.2.A or G.2.B* above.
2. The surgeon has maintained a current working knowledge of all aspects of pancreas transplantation and patient care, defined as direct involvement in pancreas transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the training program's primary surgeon and 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.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

### **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.

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. The physician must have completed at least one of the 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.

### **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 must have observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
  6. 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 designated pancreas transplant program. 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 must have observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
  5. 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.

### **C. Alternative Pathway for Predominantly Pediatric Programs**

If a physician does not meet the requirements for primary physician through 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 pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections G.3.A and G.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of pancreas transplantation, defined as direct involvement in pancreas 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 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.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

#### **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. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician must have observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
6. The program has established and documented a consulting relationship with counterparts at another pancreas 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 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.
8. 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 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.

## **G.4 Requirements for Designated Pancreatic Islet Transplant Programs**

All pancreatic islet transplant programs must meet the following criteria:

1. All of the requirements of a designated pancreas transplant program as defined in the sections above or meet the criteria for an exception as detailed in *Section G.4.D. Programs Not Located at an Approved Pancreas Transplant Program* below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

### **A. Transplant Facilities**

The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

## **B. Expert Medical Personnel**

The program must have a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon. It is further recommended that the program have on site or adequate access to:

1. A board-certified endocrinologist
2. A physician, administrator, or technician with experience in compliance with FDA regulations
3. A laboratory-based researcher with experience in pancreatic islet isolation and transplantation

Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.

## **C. Islet Isolation**

Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and the facility.

## **D. Programs Not Located at an Approved Pancreas Transplant Program**

A program that meets all requirements for a designated pancreatic islet transplant program but is not located at a hospital approved as a designated pancreas transplant program may qualify as a pancreatic islet transplant program if the following additional criteria are met:

1. The program demonstrates a documented affiliation with a designated pancreas transplant program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.
2. The program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.
3. The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. An informal discussion with the MPSC is also required.

## **G.5 Primary Pancreatic Islet Transplant Surgeon Requirements**

The program must have on site a qualified surgeon who is designated as the primary pancreatic islet transplant surgeon and meets the requirements for pancreas transplant surgeon defined in these Bylaws.

## **G.6 Primary Pancreatic Islet Transplant Physician Requirements**

The program must have on site a qualified physician who is designated as the primary pancreatic islet transplant physician and meets the requirements for pancreas transplant physician defined in these Bylaws.

## **G.7 Approved Pancreas Transplant Surgeon Fellowship Training Programs**

Surgeons qualifying as primary transplant surgeons based on completion of a formal 2-year surgical transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another

recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is located at a transplant hospital that transplants one or more organs, including pancreas.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 20 pancreas transplants during each year of fellowship training.

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

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated heart transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated heart transplant program.

This appendix does not include the general membership requirements that all transplant programs must meet, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

### **H.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician**

A heart transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and physician, along with the program director, must submit a detailed program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.6.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### **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. In the case of a surgeon who has just completed training and whose certification by the American Board of 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 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. The surgeon must have completed at least one of the 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 the surgeon's cardiothoracic surgery residency operative log. The date of transplant, role of the surgeon in the procedure, medical record number or other unique identifier that can be verified by the OPTN Contractor, and the training program director's signature must be provided with this log.
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. 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 the surgeon's cardiothoracic surgery residency operative log. The date of procurement, Donor ID, and the training program director's signature must be provided with this log.
  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.
  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 the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
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. 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 the surgeon's fellowship operative log. The date of procurement, Donor ID, and the training program director's signature must be provided with this log.

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.
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. 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 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.

#### **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 and Actions* of these Bylaws.

### **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 or current board certification in advanced heart failure and transplant cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

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. The physician must have completed at least *one* of the 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 must have observed at least 3 heart procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
5. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology, 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.
6. 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. 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 must have observed at least 3 heart procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
5. 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.

## **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 and Actions* of these Bylaws.

#### **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 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.
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 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.
3. 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.
4. The physician must have observed at least 3 heart procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  5. 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.
  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 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.

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

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated lung transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated lung transplant program.

This appendix does not include the general membership requirements that all transplant programs must meet, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

### **I.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician**

A lung transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.6.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### **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. In the case of a surgeon who has just completed training and whose certification by the American Board of

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. The surgeon must have completed at least one of the 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 the surgeon's cardiothoracic surgery residency operative log. The date of transplant, role of the surgeon in the procedure, medical record number or other unique identifier that can be verified by the OPTN Contractor, and the training program director's signature must be provided with this log.
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 the surgeon's cardiothoracic surgery residency operative log. The date of procurement and Donor ID must be provided with this log.
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.
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 the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that

- can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
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. 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 the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
  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.
  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. 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 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.

#### **D. Alternative Pathway for Predominantly Pediatric Programs**

If a surgeon does not meet the requirements for primary lung 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 lung transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections 1.2.A through 1.2.C* above.
2. The surgeon has maintained a current working knowledge of all aspects of lung transplantation and patient care, defined as direct involvement in lung 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.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

### **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.

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. The physician must have completed at least one of the 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 must have observed at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
5. 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.
6. 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 at a designated lung transplant program. 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 must have observed at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement 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.
5. 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.

### **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 lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections 1.3.A and 1.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as direct involvement in lung 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 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 of Directors.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

### **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 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.
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.
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.
  4. The physician must have observed at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  5. 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.
  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 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.

## **Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs**

This appendix describes the documentation transplant hospitals must provide when requesting approval as a designated VCA transplant program. VCAs include, but are not limited to, faces and upper extremities.

### **J.1 Letter of Notification**

If a transplant hospital member commits to performing VCA transplants the hospital must send a written notification to the OPTN Contractor that includes *both* of the following:

1. The specific type or types of VCA transplant the hospital will perform.
2. If the member will perform deceased donor VCA transplants, assurance from the local OPO that it will provide the same type or types of VCA for transplantation.

The letter of notification from the transplant hospital must be signed by *all* of the following individuals:

1. The chief administrative officer for the institution.
2. The reconstructive surgeon for each type of VCA transplant with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction.
3. The transplant physician or transplant surgeon for each type of VCA transplant at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.

The OPTN Contractor will then notify the transplant hospital member of the program designation for each type of VCA transplant.

## **Appendix K: Transplant Program Inactivity, Withdrawal, and Termination**

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

The following provisions of Appendix K do *not* apply to VCA transplant programs:

- *K.1: Transplant Program Inactivity*
- *K.2: Short-term Inactive Transplant Program Status*
- *K.3: Long-term Inactive Transplant Program Status*

### **K.1 Transplant Program Inactivity**

Transplant programs must remain active in transplantation to maintain membership in the OPTN. There are two types of member inactivity:

1. Short-term Inactivity
2. Long-term Inactivity

A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- The inability to meet functional activity requirements.
- The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days.
- Temporarily lacking required physician or surgeon coverage.
- A substantial change in operations that requires an interruption in transplantation.

For more information about the functional activity requirements for transplant programs, see *Section D.11: Review of Transplant Program Functional Activity* of these Bylaws.

#### **A. Program Component Cessation**

Programs that cease performing a specific type of transplant (e.g. the living donor component of a transplant program, or cessation of only pediatric or only adult transplants in a transplant program that performs both), must notify every patient affected by the cessation, including:

- Potential candidates, including those currently in the referral or evaluation process
- All candidates registered on the waiting list
- Potential living donors, including those currently in the referral process, in the evaluation process, or awaiting donation

<b>Ceased Component*</b>	<b>All Affected Patients Being Treated or Evaluated by the Transplant Program Including:</b>
Living Donor Component	<ul style="list-style-type: none"> <li>• Potential Living Donors</li> <li>• Potential and waitlisted candidates who have already expressed interest in LD</li> </ul>
Deceased Donor Component	<ul style="list-style-type: none"> <li>• Potential and waitlisted deceased donor candidates</li> </ul>
Adult Component	<ul style="list-style-type: none"> <li>• Potential and waitlisted adult candidates</li> <li>• Potential and waitlisted pediatric candidates who may turn 18 during the component cessation period</li> </ul>
Pediatric Component	<ul style="list-style-type: none"> <li>• Potential and waitlisted pediatric candidates</li> </ul>

\*In instances when a program elects to cease transplant for a subset of patients within a program component, such as infants in a pediatric component, the affected group would be further defined to only include that specific patient population.

For more information about the notification content and timing requirements, see *Appendix K, Section K.3: Long-term Inactive Transplant Program Status* and *Section K.4: Withdrawal or Termination of Designated Transplant Program Status* of these Bylaws.

## **K.2 Short-term Inactive Transplant Program Status**

Short-term inactivity is defined as a transplant program that is inactive for no more than 14 consecutive days. A transplant program may voluntarily inactivate for no more than 14 days by changing its UNet<sup>SM</sup> waiting list status to *inactive*.

When a member intends to voluntarily inactivate a transplant program on a short-term basis, the member is not required to notify the OPTN Contractor.

### **A. Notice to Patients**

A transplant program must provide candidates and recipients with a written summary of its Program Coverage Plan at the time of listing and any time there are substantial changes in program or personnel. If a transplant program knows that it will have periods of short-term inactivity, this should be clearly stated as part of the Program Coverage Plan provided at the time of listing. For more information about the Program Coverage Plan, see *Section D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

## **K.3 Long-term Inactive Transplant Program Status**

Long-term inactivity occurs when a transplant program is inactive for 15 or more consecutive days.

Members should voluntarily inactivate a transplant program that is not able to serve potential candidates, candidates, living donors, or recipients for 15 or more consecutive days. Voluntary inactivation may extend for a period of up to 12 months.

Long term inactivation results in an inactive waiting list status and an inactive membership status.

### **A. Notice to the OPTN Contractor of Long-term Inactive Status**

When a member will voluntarily inactivate a transplant program for 15 or more consecutive days, it must provide written notice, including the reasons for inactivation, to the OPTN Executive Director.

### **B. Notice to the Patients of Long-term Inactive Status**

When a member intends to inactivate a transplant program for 15 or more consecutive days, it must provide written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being treated by the transplant program. Written notice should be provided at least 30 days prior to the planned inactivation date by a method that can be tracked and that provides proof of receipt, such as:

- Commercial overnight delivery service
- Secure electronic communication
- Registered or certified mail, return receipt requested

Written notice must be provided no later than 7 days after inactivation and include *all* of the following:

1. The reasons for inactivating the transplant program.
2. Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is inactive.
3. Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program.
4. Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration.
5. The phone number of the inactive program's administrative office that can help with transferring to another transplant program.

The member must provide to the OPTN Contractor a sample of each type of patient notice it sends to potential candidates, candidates, recipients, and living donors along with a list of patients who received the notice.

If a natural disaster adversely affects the function of a transplant program, the patient notification requirements will be applied reasonably and flexibly.

### **C. Reactivation after Voluntary Long-term Inactive Status**

A member transplant hospital may reactivate its program after long-term voluntary inactivation by submitting the application materials required by the Membership and Professional Standards Committee (MPSC). The MPSC will decide if all criteria for membership are met and that the program can reactivate. The MPSC will then recommend that the Board of Directors notify the Secretary of Health and Human Services (HHS) of the member's reactivation.

## **D. Extension of Voluntary Long-term Inactive Status**

A transplant hospital that voluntarily inactivates may request an extension beyond 12 months by making a request to the MPSC. The request must explain how the extension will benefit the program, and include a comprehensive plan with a timeline for resuming transplantation at the hospital. The program must document that all membership criteria will be met when transplantation is resumed. Requests are subject to the MPSC's review and approval.

## **K.4 Withdrawal or Termination of Designated Transplant Program Status**

Designated transplant program withdrawal means that a member voluntarily gives up its designated transplant program status and provides written notice to the OPTN. Members that withdraw from designated transplant program status are voluntarily closing the transplant program.

Termination of designated transplant program status means that a member's designated transplant program status is terminated by the Secretary of HHS. In the case of noncompliance with policies covered by *Section 1138* of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee request approval from the Secretary to terminate a member's designated transplant program status as described in *Appendix L: Reviews and Actions* of these Bylaws. The Board of Directors or the Executive Committee may, at its own discretion, request this approval from the Secretary.

Once a member voluntarily withdraws from designated transplant program status or is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. At this time, the member must also assist candidates in transferring to another transplant program, as described in *Section K.5: Transition Plan during Long-term Inactivity, Termination, or Withdrawal* below.

### **A. Notice to the OPTN Contractor**

A transplant hospital must provide written notice to the OPTN Contractor within 30 days of the intent to withdraw its designated transplant program status, including the effective date and reasons for the withdrawal.

### **B. Notice to the Patients**

When a transplant hospital intends to withdraw its designated transplant program status, or its designated transplant program status is terminated, it must provide written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently receiving care.

Written notice should be provided at least 30 days prior to the anticipated date of withdrawal or termination by a method that can be tracked and that provides proof of receipt such as:

- Commercial overnight delivery service
- Secure electronic communication
- Registered or certified mail, return receipt requested

Written notice must be provided no later than 7 days following withdrawal or termination and include:

1. The reasons for loss of designated transplant program Status.
2. Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program.
3. Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program.
4. Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration.
5. The phone number of the program's administrative office that can help with transferring the candidate or potential candidate to another program.

The member must provide to the OPTN Contractor a sample of each type of patient notice it sends to potential candidates, candidates, recipients, and living donors along with a list of patients who received the notice.

## **K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal**

When a member transplant hospital experiences long-term inactivity, withdraws its designated transplant program status, or its designated transplant program status is terminated, it must:

1. Immediately suspend organ transplantation for the transplant program.
2. Assist potential candidates and candidates in transferring to other designated transplant programs.
3. Provide a list to the OPTN Contractor of all of the transplant program's candidates on the waiting list at the time of long-term inactivity, withdrawal, or termination and update it throughout this process. The program should indicate on the list of each candidate if:

- A candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision before they are removed from the waiting list.
- A candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic status updates will be required that documents each candidate's transfer progress until the candidate is evaluated and accepted on the waiting list by another transplant program or removed from the waiting list.
  - a. Expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN member transplant hospital.
  - b. Initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within 7 days of long-term inactivity, withdrawal, or termination. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time, or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates, if it is unable to meet these time periods.
  - c. Provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

- For liver candidates, all Status 1A and 1B candidates must be transferred within 7 days of long-term inactivity, withdrawal, or termination, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates.
- For lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates.
- For kidney candidates, those whose PRA (measured or calculated) is over 80 percent should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates last.
- For heart candidates, all pediatric status 1A and 1B and adult status 1, 2, 3, and 4 must be transferred within 7 days of long-term inactivity, withdrawal, or termination.
- For multi-visceral organ transplant candidates, transfer must be completed within 30 days of long-term inactivity, withdrawal, or termination.
- All active candidates should be transferred within 60 days of long-term inactivity, withdrawal, or termination without considering these guidelines.
- The program must document and submit to the OPTN Contractor all efforts made for transfer of its candidates if it is unable to meet these deadlines.
- Document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates.
- Remove every transplant candidate from the transplant program's waiting list within 12 months of the program's long-term inactivity, withdrawal, or termination date.

A member that experiences long-term inactivity, withdrawal, or termination of a designated transplant program may still have the ability to temporarily provide care to transplant candidates, and provide follow-up care as necessary to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms through UNet<sup>SM</sup>. Alternatively, transplant recipients may transfer care to another hospital.

## **K.6 Transferred Candidates Waiting Time**

To ensure equity in waiting times and ease the transfer of candidates from the waiting list, the candidates at programs that voluntarily inactivate, withdraw or lose designated transplant program status will:

1. Retain existing waiting time.
2. Continue to accrue waiting time according to their status on the waiting list at the time of the program's inactivation, withdrawal, or termination of designated transplant program status.

This total accrued waiting time can be transferred to the candidate's credit when the candidate is listed with a new transplant program.

The OPTN Contractor may collectively transfer patients from a transplant program, with a status of long-term inactive, withdrawal, or termination, and in other circumstances upon request to one or more active transplant programs.

The transferring transplant program must complete *all* of the following before a collective transfer:

1. All required patient notifications according to *Section K.3: Long-term Inactive Transplant Program Status* or *Section K.4: Withdrawal or Termination of Designated Transplant Program Status*.
2. A written agreement with each accepting transplant program that includes *all* of the following:
  - a. Request for collective transfer of candidates' waiting times
  - b. List of patient names and identifiers to be transferred
  - c. Mutually agreed upon transfer date
  - d. Assurance of notification and patient consent to transfer according to *Section K.5: Transition Plan during Long-term Inactivity, Termination, or Withdrawal*
  - e. List of active candidates that the transferring program agrees to change to inactive status if requested by the accepting transplant program
  - f. Acknowledgement that all patient information and records available to the OPTN Contractor will be transferred without modification
  - g. Acknowledgement that the transplant program accepting the patients accepts responsibility for patient notification and management according to all applicable OPTN Policies and Bylaws

Each accepting transplant program must develop and implement a plan that includes *all* of the following:

1. Procedure and timeline for reviewing the status on each collectively transferred candidate and amending this status as appropriate until an evaluation is completed in accordance with the accepting program's selection and listing protocol.
2. If the transferred candidate's status is changed from active to inactive as part of the collective transfer agreement or part of implementing the accepting transplant program's plan, then the accepting transplant hospital must notify the candidate about the status change. The notification must include what the candidate must do to be considered for an active status at the accepting transplant program. The notification must be completed within 14 days after the collective transfer date or after the status change date if it occurs post-collective transfer as part of this plan.
3. Expected timeline for completing evaluations and subsequent waiting list status adjustments on collective transfer candidates according to the accepting program's selection and listing protocol.

Upon receipt of the written agreement and plan, the OPTN Contractor will review the information and provide an expected collective transfer completion date to all the transplant programs involved. After the collective transfer process has been completed, the OPTN Contractor will provide written notification to the transplant programs.

The accepting hospital must submit a progress report to the OPTN Contractor that contains an update on the evaluation status of each collective transfer candidate at day 90 following the collective transfer. The accepting hospital must submit this report within 14 days after day 90 following the collective transfer. Additional updates may be requested from the OPTN Contractor to monitor progress until all collective transfer candidates are evaluated and accepted on the waiting list by a transplant program or removed from the waiting list.

If the transferring transplant program no longer qualifies as a designated transplant program and does not complete the requirements according to *Appendix K*, the OPTN Contractor may approve and complete a collective transfer of candidates' registrations and waiting times if the accepting transplant program requests in writing to complete the transfer.

## **K.7 Laboratory Tests**

If a transplant program is inactivated, terminated or withdraws from membership, it is still responsible for evaluating its candidates. This includes, but is not limited to, performing laboratory tests and evaluations required to maintain the candidate's appropriate status on the waiting list until the time of transfer.

## **Appendix L: Reviews and Actions**

By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations according to *Article 1.1: Member Requirements*. This Appendix outlines how the OPTN reviews potential noncompliance with OPTN Obligations, the process for other reviews as specified in OPTN Policies and Bylaws, and the actions the OPTN may take in response. The Appendix also describes a member's rights during OPTN reviews.

### **L.1 Methods for Correspondence**

All correspondence between members and the OPTN required by this *Appendix L* must be sent by a method that can be tracked and provides proof of receipt.

### **L.2 Representative Terminology Used throughout Appendix L**

#### **A. References to the OPTN**

Throughout this *Appendix L*, references to the OPTN include the Board of Directors, OPTN committees and subcommittees, OPTN committee members, the OPTN Executive Director, and the OPTN Contractor. Bylaws requirements that are specific to any of these groups or individuals explicitly name the group or individual.

#### **B. References to the MPSC Chair**

References to the MPSC Chair in this *Appendix L* necessarily include the possibility of an MPSC Chair designee. If the MPSC Chair cannot fulfill a duty as required in these Bylaws for any reason, such as unavailability or potential conflicts of interest, then these duties will be delegated to another individual. Selection of an MPSC Chair designee will proceed in the following order until a designee is identified:

1. MPSC Vice Chair
2. MPSC regional representatives, as selected by the OPTN President

### **L.3 Medical Peer Review**

The OPTN will conduct all deliberations and take all actions according to applicable medical peer review laws. Consistent with applicable laws, all inquiries, deliberations, recommendations, and actions during member reviews by the OPTN will be kept confidential. All proceedings and records within the scope of these OPTN quality review activities are confidential. Members of any OPTN Committee attending the meeting in which a peer review is conducted, serving as a peer reviewer, working for or on behalf of the OPTN, or providing information to the OPTN for peer review activities, are entitled to confidentiality.

The OPTN will keep all materials, information, and correspondences to and from members and directly related to the OPTN peer review process confidential to promote quality improvement and full disclosure by OPTN members. Materials, information, and correspondences created by or for the peer review body are considered "directly related."

The OPTN will not disclose any materials provided to the OPTN by the member, except as required by law. Materials prepared by members independent of the OPTN medical peer review process may be shared by members in their discretion.

#### **L.4 Conflicts of Interests**

The OPTN's Conflict of Interest Policy applies to all OPTN inquiries, deliberations, recommendations and actions during member reviews.

#### **L.5 Investigation of Potential Noncompliance with OPTN Obligations**

When the OPTN becomes aware of a member's potential noncompliance with OPTN Obligations, the OPTN will conduct an investigation. This investigation will evaluate whether a potential noncompliance exists. The investigation will also consider whether the potential noncompliance suggests a risk to patient health or public safety, and the urgency and severity of the risk.

Members must respond to all investigation requests within the specified period. A member may provide any information that it believes is relevant to the investigation. The OPTN will notify the member of the date by which the member must submit the requested or additional information.

#### **L.6 Requests to Mitigate Risks**

If an OPTN review suggests a potentially urgent or severe risk exists to patient health or public safety, the OPTN may ask that the member take appropriate actions to mitigate the urgency and severity of the risk. A member's failure to sufficiently mitigate the risk in the period requested will be considered a separate potential noncompliance with OPTN Obligations.

#### **L.7 Scheduling MPSC and Member Interactions**

Members currently under MPSC review may be offered specific opportunities, in the form of informal discussions, interviews, and hearings, to interact with the MPSC. The MPSC Chair will determine when these interactions will be scheduled. Factors that will influence the scheduling of these MPSC and member interactions include, but are not limited to, *any* of the following:

- The urgency and severity of the issue
- Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- Adequate time for members to demonstrate the results and sustainability of their containment and corrective action plans
- The MPSC's meeting schedule

The OPTN will notify the member when the MPSC is offering an informal discussion, interview, or hearing. The OPTN's offer notice will include *all* of the following:

1. The reasons the MPSC is offering the member an interaction
2. The date by which the member must accept or decline the MPSC's offer
3. A list of any information the OPTN would like the member to submit in advance of the interaction
4. A summary of what the member should address during the interaction

#### **L.8 Informal Discussions**

An informal discussion is a direct conversation between a group of MPSC members and a member currently under MPSC review. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. Informal discussions are information gathering activities that may lead to a more efficient and effective review than written correspondence and document reviews alone.

## **A. Member Informal Discussion Requests**

A member currently under review by the MPSC may request an informal discussion at any time. Members requesting an informal discussion must submit *all* of the following:

1. The reasons the member is requesting an informal discussion, including the applicable OPTN Policy or Bylaw
2. A summary of what the member would like to present to the MPSC, or what the member would like the MPSC to address during the informal discussion
3. Any information the member would like the MPSC to consider in advance of the informal discussion

The MPSC Chair will accept or decline a member's request for an informal discussion with the MPSC within 14 days of receiving the member's request. The OPTN will notify the member of the MPSC Chair's decision.

## **B. MPSC Informal Discussion Requests**

The MPSC or MPSC Chair may offer members currently under review one or more informal discussions at any time. A transplant program is entitled to an informal discussion before the MPSC recommends that the program inactivate or withdraw its designated transplant program status due to functional inactivity or transplant program performance reviews according to *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.

## **C. Waiving an Informal Discussion**

Members that decline the MPSC's informal discussion request may submit additional written information for the MPSC's review. The MPSC Chair will set a date by which the member must provide any additional written information.

Members that decline an MPSC informal discussion request do not waive their right to future interactions with the MPSC, including interviews and hearings.

## **D. Informal Discussion Format**

Informal discussions will be conducted by teleconference and will include:

1. At least 10 minutes for the member to present information
2. At least 15 minutes for the member to respond to questions from the MPSC
3. At least 4 MPSC members

## **E. Informal Discussion Outcome**

Within 21 days, the OPTN will provide the member with a written summary of the informal discussion.

The group that conducted the informal discussion may request that the member submit additional information for the MPSC's review after the informal discussion, but will not take an action as outlined in *Section L.12: OPTN Actions*. The group will report its findings to the MPSC, along with any additional materials requested, no later than the MPSC's next in-person meeting. Following this report, the MPSC will continue its review and will notify the member of any decisions or actions, including the reasons for the MPSC's decision.

## L.9 Interviews

An interview is an opportunity for the MPSC and member to discuss an ongoing review. During an interview, the member has the opportunity to present information, including any steps the member has taken to correct the issue and to address any concerns the MPSC shared with the member prior to the interview. The MPSC will ask the member questions and will determine an appropriate action based on the interview findings.

### A. Right to an Interview

The MPSC or MPSC Chair may offer a member currently under MPSC review one or more interviews at any time.

The member has the right to an interview:

1. Before the MPSC recommends that the Board of Directors places a member on Probation or declares a member Not in Good Standing
2. If the MPSC rejects a member's request for release from Probation or Member Not in Good Standing
3. If the MPSC recommends that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
4. If the MPSC rejects a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

### B. Waiving an Interview

Members that do not respond to the interview offer by the specified date waive their right to an interview.

Members that waive their right to an interview with the MPSC also:

- Waive their right to a hearing
- Waive their right to appear before the Board of Directors

Members that waive their right to an interview must still respond to any MPSC requests for written information and may provide additional written information for the MPSC to review. The MPSC Chair will set a date by which the member must provide any additional written information.

### C. Interview Format

Interviews may be conducted by teleconference or at an in-person MPSC meeting, as determined by the MPSC Chair. Interviews will include:

1. At least 15 minutes for the member to present information
2. At least 30 minutes for the member to respond to questions from the MPSC
3. At least 10 MPSC members, which shall constitute a quorum for the purpose of any actions resulting from the interview.

At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue that is the subject of the review. If there are not at least 2 subject matter experts available from the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN

committees. These individuals may participate in all aspects of the interview process, but they serve in an advisory role and do not have a vote.

#### **D. Possible Interview Outcomes**

Following the interview, the MPSC will determine an appropriate action and notify the member of the interview outcome. Within 21 days of the interview, the OPTN will provide the member with documentation of the reasons for the MPSC's decision and a written summary of the interview.

If the MPSC considers recommending an adverse action, then the member will be entitled to a hearing with the MPSC before the MPSC forwards its recommendation to the Board of Directors.

### **L.10 Hearings**

The MPSC will offer hearings to members when the MPSC is considering recommending that the Board of Directors takes certain actions. Hearings are formal procedures during which the OPTN presents information explaining the rationale for its recommendation. Hearings are the final opportunity for the member to present information for the MPSC to consider before the MPSC makes its recommendation to the Board of Directors.

#### **A Right to a Hearing**

The member has the right to a hearing if the member participated in an interview and:

1. Before the MPSC recommends that the Board of Directors places a member on Probation or declares a member Not in Good Standing
2. The MPSC rejects a member's request for release from Probation or Member Not in Good Standing
3. The MPSC recommends that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
4. The MPSC rejects a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

#### **B. Waiving a Hearing**

Members that do not respond to the hearing offer by the specified date waive their right to a hearing.

Members that waive their right to a hearing with the MPSC also:

- Accept the MPSC's recommendation
- Waive their right to appear before the Board of Directors

Members that waive their right to a hearing must still respond to any MPSC requests for written information and may provide any additional written information for the MPSC to consider. The MPSC Chair will set a date by which the member must provide any additional written information.

#### **C. Hearing Format**

Hearings will be conducted during an in-person MPSC meeting. The member and the OPTN have the right to be represented by an attorney during a hearing.

Hearings include *all* of the following:

1. Equal time for the member and the OPTN to present information
2. At least 60 minutes for the member to present information
3. At least 60 minutes for the OPTN to present information
4. At least 60 minutes for the MPSC to question any member and OPTN representatives present at the hearing
5. At least 10 MPSC members, which shall constitute a quorum for the purpose of any actions resulting from the hearing.

At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue that is the subject of the review. If there are not at least 2 subject matter experts available from the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN committees. These individuals may participate in all aspects of the hearing process, but they serve in an advisory role and do not have a vote.

#### **D. Possible Hearing Outcomes**

Following the hearing, the MPSC will determine an appropriate action and notify the member of the hearing outcome. Within 21 days of the hearing, the OPTN will provide the member with documentation of the reasons for the MPSC's decision and a transcript of the hearing.

If the MPSC recommends an adverse action, then the member will be entitled to appear before the Board of Directors.

If the MPSC determines the matter represents a potentially urgent and severe risk to patient health or public safety, the MPSC may recommend to the OPTN President that the OPTN Executive Committee considers the MPSC's recommendation to allow for a more timely resolution of the matter. The OPTN will notify the member following the hearing if the MPSC's recommendation also includes a recommendation that the OPTN Executive Committee considers the recommendation.

### **L.11 Appearances before the Board of Directors**

Members and the MPSC Chair may appear before the Board of Directors prior to the Board of Directors taking a final action on an MPSC recommendation. Appearances before the Board of Directors are formal procedures that provide an opportunity for the MPSC Chair to explain the MPSC's recommendation and for a member to present specific reasons as to why the Board of Directors should not support the MPSC's recommendation.

If the OPTN President determines that an urgent and severe risk to patient health or public safety exists and that allowing the OPTN Executive Committee to consider the recommendation will allow for a more timely resolution of the matter, the OPTN President may permit the appearance to take place before the OPTN Executive Committee instead of the Board of Directors. In these instances, all requirements, considerations, and actions described in the sections that follow that pertain to appearances before the Board of Directors will apply to appearances before the OPTN Executive Committee.

#### **A. Right to Appear before the Board of Directors**

A member has the right to appear before the Board of Directors if the member has participated in a hearing and afterwards *one* of the following conditions is met:

- The MPSC recommended that the Board of Directors places the member on Probation or declares a member Not in Good Standing
- The MPSC rejected a member's request to be released from Probation or Member Not in Good Standing
- The MPSC recommended that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
- The MPSC rejected a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

## **B. Accepting or Waiving a Board of Directors Appearance**

Members must accept or waive their right to appear before the Board of Directors within the period specified. Members that fail to respond to the offer of a Board of Directors appearance within the specified period waive their right to appear.

At the same time the member accepts its right to appear before the Board of Directors, the member must also provide its specific disagreements with the OPTN's findings of fact, conclusions, or procedural issues that the member plans to contest before the Board of Directors.

Members that waive their right to appear accept the MPSC's adverse action recommendation. Members that waive their right to appear may provide additional written information for the Board of Directors to consider. The OPTN President will set a date by which the member must provide any additional written information.

## **C. Scheduling a Board of Directors Appearance**

The OPTN President will determine when a member's appearance before the Board of Directors will occur. Factors that will influence the scheduling of a member's Board of Directors appearance include, but are not limited to, *any* of the following:

- The urgency and severity of the issue
- Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- The Board of Directors' meeting schedule

The OPTN will notify the member when the member is entitled to an appearance before the Board of Directors. The OPTN's offer notice will include *all* of the following:

1. The reason the member is entitled to an appearance before the Board of Directors
2. The reasons for the MPSC's recommendation to the Board of Directors
3. The date by which the member must accept or decline the offer
4. A summary of what the member should address during the interaction

## **D. Board of Directors Appearance Format**

A member's appearance before the Board of Directors may be by teleconference or at an in-person Board of Directors meeting, as determined by the OPTN President.

The member and the OPTN have the right to be represented by an attorney during a Board of Directors appearance.

Board of Directors appearances include *all* of the following:

1. Equal time for the member and the MPSC Chair to present
2. At least 10 minutes for the member to present information to the Board of Directors
3. At least 10 minutes for the MPSC Chair to present information to the Board of Directors
4. At least 15 minutes for the Board of Directors to ask questions of the member and MPSC Chair

A majority vote of the Directors present at any meeting at which a quorum is present is required to approve an adverse action.

#### **E. Burden of Proof**

Appearances before the Board of Directors are to address specific disagreements with the findings of fact, conclusions, or procedural issues raised at any step in the review process. The member will have the burden of proving that the MPSC's recommendation lacks substantial basis or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious.

#### **F. Possible Board of Directors Appearance Outcomes**

At the conclusion of the Board of Directors appearance, the Board of Directors will approve the MPSC's recommendation or issue a lesser action and will notify the member of the outcome. Within 21 days of the Board of Directors appearance, the OPTN will provide the member with a written summary of the Board of Directors appearance.

If the Board of Directors approves an adverse action, the OPTN will issue a public notice and the member must provide additional notice within 30 days of receiving the Board of Directors appearance summary as required according to *Section L.12.D: OPTN Adverse Actions*.

### **L.12 OPTN Actions**

The OPTN may impose actions based on a member's failure to comply with OPTN Obligations. The OPTN may impose a separate action for each noncompliance or may choose to impose a single action for all related instances of noncompliance. The OPTN may also require a member to perform specific activities to address a noncompliance. The OPTN will document all actions in the member's compliance history.

#### **A. Deferred Disposition**

Deferred Disposition is a period to allow the member additional time to demonstrate improvement and its ability and willingness to meet OPTN Obligations. Only the MPSC may offer a member a Deferred Disposition period. The MPSC may offer a Deferred Disposition period at any time before a hearing and may offer a member more than one Deferred Disposition period during a review. Deferred Disposition does not apply to rejected membership applications.

During this period, the member must demonstrate compliance with OPTN Obligations, including implementation of and adherence to the member's corrective action plan or plan for quality improvement. The MPSC will specify the length of the Deferred Disposition period, and may end the Deferred Disposition period at any time if the MPSC determines, at its discretion, the member is not demonstrating sufficient improvement or is not adhering to the member's corrective action plan or plan for quality improvement. After the Deferred Disposition period, the MPSC will evaluate whether the member has demonstrated improvement and implemented sustainable corrective actions and will determine an appropriate action.

The member is not entitled to an informal discussion, interview, hearing or Board of Directors appearance to challenge the MPSC's decision not to offer, or to end, a Deferred Disposition period.

## **B. Types of Actions**

The OPTN may offer Deferred Disposition or take *any* of the following actions:

- Close with No Action
- Issue a Notice of Noncompliance
- Issue a Letter of Warning
- Place a member on Probation
- Declare a member Not in Good Standing

These actions represent a range, from Close with No Action to Member Not in Good Standing. Close with No Action, Issuing a Notice of Noncompliance, and Issuing a Letter of Warning are non-adverse actions. Non-adverse actions do not require approval by the Board of Directors and are not made public. Probation and Member Not in Good Standing are adverse actions. Adverse actions are further described in *Section L.12.D: OPTN Adverse Actions*.

## **C. Determining Appropriate Action**

Factors considered when determining the appropriate action include, but are not limited to, the extent to which:

- The member has demonstrated an awareness of and accountability for the noncompliance, including:
  - whether the member self-reported the noncompliance
  - whether the member took corrective action when learning of the noncompliance
- The noncompliance poses an urgent and severe risk to patient health or public safety
- The noncompliance poses or fails to avoid a substantial risk to the integrity of or trust in the OPTN
- Patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the noncompliance occurred
- The noncompliance demonstrates lack of stewardship of donated organs
- The noncompliance is likely to recur
- The member has demonstrated previous and ongoing compliance with OPTN Obligations

## **D. OPTN Adverse Actions**

Probation and Member Not in Good Standing are the two OPTN adverse actions. Adverse actions are OPTN membership designations that must be approved by the Board of Directors and require public notice.

A member's ongoing failure to comply with OPTN Obligations or a member's failure to promptly address a potentially urgent and severe risk to patient health or public safety may result in the MPSC recommending that the Board of Directors takes an adverse action against the member.

Before the Board of Directors approves an adverse action, members have the right to an interview and a hearing with the MPSC and an appearance with the Board of Directors.

The Executive Committee will consider MPSC recommendations to release a member from an adverse action.

**1. Probation**

**a. Loss of OPTN Privileges**

Members placed on Probation do not lose any OPTN membership privileges.

**b. Probation Notification Requirements**

When the Board of Directors places a member on Probation, the OPTN will provide notice to the public. This may include but is not limited to communication using the OPTN website. The OPTN may issue other public notices about the Probation as determined by the Board of Directors.

At its discretion, and based on the circumstances surrounding the noncompliance, the MPSC may recommend that the Board of Directors suspends, modifies, or adds to the requirements regarding the notice that members on Probation must provide. After the OPTN notifies the member that it has been placed on Probation, the member must provide notice within 30 days as instructed by the Board of Directors, if the Board of Directors acted on an MPSC recommendation regarding providing notice. If the MPSC did not provide, or the Board of Directors did not act on, recommendations for providing notice, then the member must provide notice within 30 days according to Table L-1 below.

**Table L-1: Probation Notification Requirements**

<b>If the member is a...</b>	<b>Then the member must provide notice to ...</b>
Transplant hospital	All patients, as defined in these Bylaws, of the designated transplant program receiving Probation, including any new transplant program patients, during the entire Probation period. The notices must be provided in writing in each patient's spoken language, and as specified by the Executive Committee or Board of Directors. The transplant program must retain a copy of the notification letter it provided to each individual patient.
OPO	All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the laboratory.

These notices must communicate that the Board of Directors has placed the member on Probation and must also refer to the public notice about this action distributed by the OPTN.

The member must provide the OPTN Contractor a list of each patient and organization to whom it sent notice, along with an example of the notice it sent, by the date specified by the OPTN Contractor.

**c. Probation Monitoring Requirements**

**The MPSC will monitor members throughout the Probation period.**

**2. Member Not in Good Standing**

**a. Loss of OPTN Privileges**

Members Not in Good Standing are prohibited from voting in OPTN matters and any personnel associated with the member are prohibited from serving on OPTN Committees and the Board of Directors. However, members designated Members Not in Good Standing must continue to comply with their OPTN member responsibilities.

**b. Member Not in Good Standing Notification Requirements**

When the Board of Directors declares a member Not in Good Standing, the OPTN will provide notice to the public. This may include but is not limited to communication using the OPTN website. The OPTN may issue other public notices about the Member Not in Good Standing designation as determined by the Board of Directors.

After the OPTN notifies the member that it has been declared Not in Good Standing, the member must provide notice within 30 days according to Table L-2 below.

**Table L-2: Member Not in Good Standing Notification Requirements**

<b>If the member is a...</b>	<b>Then the member must provide notice to ...</b>
Transplant hospital	All transplant hospital patients as defined in these Bylaws, including any new transplant hospital patients, during the entire effective period of the Member Not in Good Standing designation. The notices must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors. The transplant program must retain a copy of the notification letter it provided to each individual patient.
OPO	All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the laboratory.

These notices must communicate that the Board of Directors has declared the member Not in Good Standing and must also refer to the public notice about this action distributed by the OPTN.

The member must provide the OPTN Contractor a list of each patient and organization to whom it sent notice, along with an example of the notice it sent, by the date specified by the OPTN Contractor.

**c. Member Not in Good Standing Monitoring Requirements**

The MPSC will monitor members throughout the Member Not in Good Standing period, which will include the following:

- One or more unannounced on-site reviews
- One or more presentations by the member before the MPSC to provide an update on the member's corrective action plan and ongoing compliance with OPTN Obligations

**3. Release from Probation or Member Not in Good Standing**

**a. Request for Release**

A member on Probation or a Member Not in Good Standing must submit a written request to the OPTN requesting release from the adverse action. The MPSC will consider the member's request and will forward any recommendations

to release a member from an adverse action to the Executive Committee for approval.

A member on Probation or a Member Not in Good Standing may request release from the adverse action when at least nine months have passed since *both* of the following occurred:

1. The MPSC approved the member's corrective action plan
2. The Board of Directors approved the adverse action

The MPSC may consider member requests to be released from an adverse action at any MPSC meeting where a quorum is present.

**b. Burden of Proof for Release**

When determining whether to release a member from Probation or a Member Not in Good Standing, the MPSC will consider whether the member can demonstrate *all* of the following:

1. It has implemented and adhered to its corrective action plan
2. Its corrective action plan is effective and sustainable
3. Its ongoing compliance with OPTN Obligations

The burden is on the member at all times to demonstrate that release from Probation or Member Not in Good Standing is appropriate.

**c. Possible MPSC Review Outcomes**

If the MPSC approves the member's request for release from Probation or Member Not in Good Standing, the MPSC will forward its recommendation to the OPTN Executive Committee. The OPTN President will determine the time and format for the OPTN Executive Committee to consider the MPSC's request.

If the MPSC rejects the member's request for release from Probation or Member Not in Good Standing, the MPSC must offer the member an interview.

**d. Possible OPTN Executive Committee Review Outcomes**

The OPTN President will determine the time and format, either in person or by teleconference, of the review. The OPTN Executive Committee will act on the MPSC's recommendation within 45 days of the date that the MPSC recommends the action.

If the OPTN Executive Committee approves the MPSC's recommendation and releases the member from Probation or Member Not in Good Standing, the OPTN will provide notice to the public. This may include, but is not limited to, communication using the OPTN website. The MPSC may still require ongoing monitoring of the member even after the OPTN Executive Committee has released the member from Probation or Member Not in Good Standing.

If the OPTN Executive Committee rejects the MPSC's recommendation to release the member from Probation or Member Not in Good Standing, the OPTN will provide the member with a written summary of the reasons for declining the MPSC's recommendation. The member may submit another request to be released from Probation or Member Not in Good Standing to the MPSC only after it has addressed all of the reasons that the OPTN Executive Committee declined the MPSC's recommendation.

#### **4. Downgrading Member Not in Good Standing**

At its discretion, the MPSC may recommend that the Board of Directors downgrades a Member Not in Good Standing designation to Probation. The OPTN President will determine the time and format for the OPTN Board of Directors to consider the MPSC's request.

The burden is on the member at all times to demonstrate that the lesser adverse action is appropriate. The member is not entitled to an informal discussion, an interview, a hearing or a Board of Directors appearance if the MPSC or the Board of Directors does not support downgrading the Member Not in Good Standing to Probation.

If the Board of Directors downgrades a Member Not in Good Standing to Probation, the OPTN will provide notice to the public. This may include, but is not limited to, communication using the OPTN website. After the OPTN notifies the member that it has been downgraded to Probation, the member:

1. Will regain the ability to vote in OPTN matters
2. Will regain the ability for any personnel associated with the member to serve on OPTN committees and the OPTN Board of Directors
3. Must comply with all Probation notification requirements
4. May request release from Probation when at least 3 months have passed since the Board of Directors downgraded the member to Probation

### **L.13 Secretary of HHS Notice and Actions**

#### **A. Secretary's Access to Information**

The medical peer review privilege will not be extended to withhold any document from the Secretary of HHS, or the Secretary's designee. The OPTN Contractor is required to provide the Secretary with any information acquired or produced under the OPTN Contract, including information that would otherwise be protected by the medical peer review privilege. As specified in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the Secretary that the Secretary requests, in the format requested by the Secretary.

#### **B. Health Resources and Services Administration (HRSA) Representation**

The Project Officer for the OPTN Contract and the Director of the Division of Transplantation within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex-officio*, non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting members of the Executive Committee and Board of Directors, they, or their designees, are granted full access to all deliberations, determinations, and actions. Representatives of HRSA are also *ex-officio*, non-voting members of the Membership and Professional Standards Committee (MPSC) and granted full access to all MPSC deliberations, determinations, and actions as well. Other designees of the Secretary may also attend OPTN meetings.

#### **C. Special Secretarial Reviews**

At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when the Secretary has reason to believe that the member may not be in compliance with the OPTN Final Rule or may be acting in a way that poses a risk to patient health or public safety. A Special Review is a review of the member in the manner and within the period specified by the Secretary. This may include, but is not limited to, requests for root cause analysis, corrective action, and due

process proceedings completed in the period and as specified by the Secretary. Members must fully comply with all OPTN Contractor requests as part of a Special Review.

#### **D. OPTN Recommendations and Requests to the Secretary**

The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic reviews and evaluations, or Secretarial-directed reviews, of member OPOs and transplant hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN Obligations or indicate a risk to the health of patients or to the public safety, and will provide any recommendations for appropriate action by the Secretary. Appropriate actions include, but are not limited to, those described in the OPTN Final Rule, as described in Section *L.13.E Secretarial Actions* that follows.

At any time, the Board of Directors may make recommendations to the Secretary for specific actions, on its own or after receiving a recommendation from the MPSC.

A member's failure to come into compliance with OPTN Obligations while designated as a Member Not in Good Standing may result in the Board of Directors recommending that the Secretary take action against the member.

If the Board of Directors finds, based on available evidence, that the member's potential violation poses a severe and urgent risk to patient health or public safety, the Board of Directors may recommend that a Secretarial action be made effective immediately, before completing any required interview or hearing.

#### **E. Secretarial Actions**

The Secretary may impose sanctions or take other appropriate action at any time when a member poses a risk to the health of patients or to the public safety.

Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:

1. Violates the National Organ Transplant Act (NOTA).
2. Violates the OPTN Final Rule, *42 CFR Part 121*.
3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more information on mandatory policies, see *Section L.13.F: OPTN Policies Approved by the Secretary as Mandatory*.
4. Engages in behavior that poses a risk to patient health or public safety.

Termination of membership requires Secretarial approval. Membership can only be terminated if the OPTN member no longer meets the requirements for membership as described in the OPTN Final Rule.

In addition to termination of membership in the OPTN described above, the Secretary may take appropriate actions, which include, but are not limited to:

1. Removal of one or more of the member's designated transplant programs. After designated transplant program status is removed, the program will no longer be eligible to receive organs for transplantation within the OPTN.
2. Termination of the member's reimbursement under Medicare or Medicaid.
3. Termination of a transplant hospital's participation in Medicare or Medicaid.
4. Request for information from the OPTN.
5. Any other action that the Secretary considers necessary.

If Secretarial action has been taken against a member, only the Secretary of HHS can restore its unrestricted membership privileges. If Secretarial action has been taken against a member and

the member has presented evidence to the MPSC that it has fully complied with OPTN Obligations, including completion of any actions prescribed as a result of the adverse action, the MPSC may recommend that the Secretary of HHS restore unrestricted membership privileges. If a membership was suspended or terminated by the Secretary, the member must complete and submit an application for OPTN membership.

Actions recommended by the OPTN Board of Directors and taken by the Secretary for noncompliance with mandatory policies will not become effective until the member has waived its right to a hearing or the applicable hearing proceedings have been concluded.

## **F. OPTN Policies Approved by the Secretary as Mandatory**

When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other actions by the Secretary.

Section 121.11(b)(2) of the OPTN Final Rule requires OPTN members that are OPOs and transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary certain information in the form required and in accordance with the schedule prescribed.

Data specified by the Secretary under this authority includes all data requested on forms approved by the Office of Management and Budget (OMB), including all applications reviewed by the OPTN. The Secretary may take an action described above for failure of a member to submit accurate and complete data as required by the Secretary (including on OMB-approved forms). Failure to submit accurate and complete data may also result in civil or criminal penalties.

## **L.14 Costs and Expenses**

### **A. Reimbursement of OPTN Contractor Costs and Expenses**

Reasonable costs and expenses of conducting interviews and hearings as described in these Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to *all* of the following:

1. Travel and lodging expenses of member, volunteers, and OPTN Contractor representatives
2. Compensation of OPTN Contractor representatives
3. Court reporter fees
4. The costs of preparing copies of the hearing record
5. The member's costs of preparing for and attending the interview or hearing
6. The OPTN's costs of obtaining and compiling evidence and exhibits

OPTN Contractor representatives may include:

- OPTN Contractor staff
- Outside counsel
- Consultants
- Volunteers
- Expert witnesses

The OPTN will decide the nature and amount of expenses to be reimbursed. Reasonable costs and expenses may be estimated and billed, wholly or partially, to the member in advance or may be billed, wholly or partially, to the member as the matter is reviewed. If actual costs and

expenses otherwise reimbursable by the member for the entire matter before the MPSC are less than \$500.00, or if member is not determined to be in violation of OPTN Obligations, no reimbursement will be due from the member. In addition, any amounts previously reimbursed or deposited will be returned. If the member has multiple matters before the MPSC within any 12-month period, the \$500.00 amount will apply to all such matters cumulatively.

## **B. Reasonable Costs and Expenses**

Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be reimbursed by the member, including *any* of the following:

1. Conducting other than routine on-site reviews
2. Reviewing and monitoring corrective action plans or plans for quality improvement
3. Conducting due process proceedings
4. Monitoring and conducting evaluations of transplant programs with lower than expected survival rates as described in *Section D.12.A: Transplant Program Performance* of these Bylaws, including on-site visits and monitoring plans for quality improvement

## **C. Advanced Deposit for Reimbursable Costs and Expenses**

The Executive Director may require that the member make and maintain a deposit with the OPTN Contractor in an amount equal to the currently projected costs and expenses of any of the following:

1. OPTN Contractor on-site reviews
2. OPTN member peer on-site reviews
3. The interview
4. The hearing

The failure to make the required deposit within 10 days after the Executive Director requests an advance deposit will be considered a waiver of the member's interview or hearing rights. Following such a waiver, the MPSC and the Board of Directors may impose any actions, including adverse actions.

## **D. Default in Payment of Reimbursable Cost and Expenses**

Any member who fails to reimburse costs and expenses within 30 days after receiving notice may be referred to the Secretary for termination of OPTN membership.

## **Appendix M: Definitions**

### **A**

#### **Ad Hoc Committees**

Ad Hoc Committees are designated in the OPTN Bylaws and are made up of transplant professionals, HRSA representatives, transplant patients, living donors, and members of the public. Unlike the OPTN permanent standing Committees, Ad Hoc Committees do not have representatives designated by each of the OPTN regions. See also *Committees*.

#### **Associate Councillor**

The associate councillor serves as the regional representative on the OPTN membership and Professional Standards Committee, assists the regional councillor with regional activities, provides leadership to the region in the absence of the regional councillor, and participates in all regional meetings. Each region elects an associate councillor who will eventually succeed the regional councillor.

#### **At-large Committee Member**

An at-large member or representative represents the general membership or the public on issues of interest or concern. An at-large member of a committee may also be appointed to provide a certain type of expertise to the committee.

### **B**

#### **Board of Directors**

The OPTN Board of Directors is the governing body for the OPTN. Directors are elected by the members of the OPTN for two or three-year terms. The general composition of the Board of Directors is set forth in the OPTN Final Rule and includes transplant professionals, HRSA representatives, members of the public, living donors, transplant candidates, recipients, and their families.

#### **Business Members**

A membership category of the OPTN. A business member is an organization in operation for at least one year that engages in commercial activities with two or more active OPTN transplant hospital, OPO, or histocompatibility laboratory members.

### **C**

#### **Corrective Action Plan (CAP)**

Corrective Action is an action taken to correct noncompliance or other violations of OPTN Obligations. A CAP is a plan that includes changes that must be made to bring expected future performance of a member in compliance with OPTN Obligations and to correct the cause of the detected error or deficiency.

**CMS, see Centers for Medicare & Medicaid Services.**

**Candidate**

A person registered on the organ transplant waiting list. When an organ is offered for the candidate, the candidate is then referred to as a Potential Transplant Recipient (PTR). References in these Bylaws to candidates include potential candidates as applicable. See also *Potential Candidate*.

**Centers for Medicare & Medicaid Services (CMS)**

CMS is an agency of the U.S. Department of Health and Human Services (HHS) responsible for administering the Medicare and Medicaid programs, which provide health care coverage to America's aged, disabled and indigent populations.

**Charter, see *OPTN Charter*.**

**Committees**

The OPTN currently maintains approximately 20 permanent and ad hoc Committees made up of transplant professionals, HRSA representatives, members of the public, living donors, transplant candidates, recipients and their families. Committees, other than the Policy Oversight Committee, also include representatives from each of the 11 regions. Each Committee is provided administrative, policy, analytic, and technical support by one or more committee liaisons from the OPTN Contractor staff. Also known as *Permanent Standing Committees*.

**Councillor**

Councillors serve as each region's representative on the Board of Directors. The councillor from each region is responsible, along with the president and the Executive Director, for coordinating regional activities to transact the business of the OPTN.

**D**

**DSA, see Donation Service Area.**

**Designated Transplant Program**

An organ-specific program that has been approved by the MPSC to as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, intestines, and vascularized composite allografts. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

**Division of Transplantation (DoT)**

A department within the Health Resources and Services Administration (HRSA) that oversees the OPTN and SRTR through contracts with private, not-for-profit corporations.

**Donation Service Area (DSA)**

The geographic area designated by the CMS that is served by one organ procurement organization (OPO), one or more transplant centers, and one or more donor hospitals.

## **Donor**

Someone who donates at least one organ or tissue for the purpose of transplantation. A deceased donor is a patient who has been declared dead using either brain death or cardiac death criteria, from whom at least one vascularized solid organ is recovered for the purpose of organ transplantation. A living donor is one who donates an organ or segment of an organ for transplantation.

## **Donor ID**

An OPTN computer generated ID that is assigned to each donor after the donor has been registered in the OPTN computer system. The Donor ID provides a unique identifier that protects the confidentiality of the donor throughout the organ procurement and transplant process.

## **E**

### **Event**

Any death or graft loss that occurred within one year of transplant.

## **F**

### **Final Rule**

The Final Rule (42 CFR Part 121) effective March 16, 2000, further defines the terms and conditions for operation of the OPTN. The Final Rule defines a standard framework for policies, requiring the OPTN to establish policy criteria, policy objectives and performance measures with procedures for continuous evaluation and reporting.

## **H**

**HHS, see Health and Human Services (HHS).**

**HRSA, see Health Resources and Services Administration (HRSA).**

### **Health and Human Services (HHS)**

The United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HRSA is a division of HHS.

### **Health Resources and Services Administration (HRSA)**

The primary healthcare agency of the Federal Government that deals with health access issues. Its role is to make essential primary care service available to poor, uninsured and geographically underserved populations. HRSA is a division of the U.S. Department of Health and Human Services (HHS). The Division of Transplantation (DoT) is a component of HRSA's Healthcare Systems Bureau (HSB). HRSA provides funding for the OPTN Contract.

## **Histocompatibility**

Tissue compatibility. Laboratories perform tests to determine the degree of histocompatibility between donor organs and potential recipients. With full histocompatibility between a donor and recipient, tissue can be transplanted without being rejected by the immune system of the recipient.

## **Histocompatibility Laboratory Member**

A histocompatibility laboratory member is a member of the OPTN. A histocompatibility member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, HLA typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO. Histocompatibility laboratory members are either independent or hospital-based. See also *independent Histocompatibility Laboratory* and *Hospital-based Histocompatibility Laboratory*.

## **Hospital-based Histocompatibility Laboratory**

A histocompatibility laboratory that is not independent from the transplant hospital it serves. Hospital-based histocompatibility laboratories are held to the same standards and requirements as histocompatibility laboratory members, but do not have a vote on OPTN business separate from the vote granted the transplant hospital member with whom it is associated. See also *histocompatibility laboratory* and *independent histocompatibility laboratory*.

## **Hospital-based OPO**

A hospital-based OPO receives financial support from the transplant hospital where it resides, or the transplant hospital provides supervision over the operations to the extent that it represents control over the hospital-based OPO's operations. Hospital-based OPOs are held to the same standards and requirements as OPO members.

See also *independent OPO* and *OPO member*.

**I**

**IOPO, see independent OPO.**

## **Independent Histocompatibility Laboratory**

An independent histocompatibility laboratory is one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves. A histocompatibility laboratory member must be an independent histocompatibility laboratory to have a vote on OPTN business. See also *Hospital-based histocompatibility laboratory member*.

## **Independent OPO (IOPO)**

An OPO that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves. See also *Hospital-based OPO* and *OPO member*.

## **Individual Member**

A membership category in the OPTN for people with an interest or expertise in the fields of organ donation or transplantation.

## **K**

### **Key Personnel**

Key personnel are those personnel that are required to be on staff at a transplant hospital, histocompatibility laboratory or OPO to qualify for and maintain membership in the OPTN. Members must notify the OPTN when there is any change in key personnel, and submit the required Personnel Change Application or written notice to the OPTN Contractor.

## **M**

**MPSC, see Membership and Professional Standards Committee.**

### **Medical/Scientific Member**

A membership category in the OPTN. A Medical/scientific member is a non-profit organization whose members include medical or scientific professionals with an interest in organ donation or transplantation.

### **Member Elector**

Public organization and individual members have voting privileges in the OPTN through member electors they elect to represent them. Each member elector is entitled to one vote on OPTN business brought before the Board.

### **Membership and Professional Standards Committee (MPSC)**

The standing OPTN committee charged with reviewing and evaluating whether OPTN members meet and remain in compliance with OPTN obligations. The MPSC reviews membership applications, and makes recommendations to the Board on membership applications. The MPSC monitors members for compliance with OPTN obligations and reviews reported violations. The MPSC may make recommendations for new membership requirements or modifications to existing requirements, and makes recommendations to the Board of Directors regarding these requirements.

### **Members**

References in these Bylaws to *members* include members of the OPTN in all seven OPTN membership categories. The OPTN membership categories are transplant hospital members, organ procurement organization (OPO) members, histocompatibility laboratory members, medical/scientific members, public organization members, business members, and individual members.

### **Multi-visceral**

A transplant procedure involving the transplant of one or more organs, such as the kidney, pancreas, liver and small intestine.

## **N**

### **National Organ Transplant Act (NOTA), 42 U.S.C. §273 et seq.**

In 1984 the national Organ Transplantation Act (NOTA) as enacted. NOTA established the basic requirements for OPOs, the OPTN, and the Scientific Registry for Transplant Recipients (SRTR). NOTA also directed the Secretary of HHS to establish by contract the Organ Procurement and Transplantation Network (OPTN) that shall be a private, non-profit entity that has an expertise in organ procurement and

transplantation. In addition, NOTA contains a criminal prohibition against the transfer of human organs for valuable consideration.

## O

**Obligations, see OPTN Obligations.**

### OPO

OPOs, or organ procurement organizations, recover organs from donors that are allocated to transplant candidates on the OPTN computer-based waiting list. See also *OPO member* and *independent OPO (IOPO)*.

**OPTN, see Organ Procurement and Transplantation Network.**

### OPTN Charter

The OPTN Charter establishes the purpose and structure of the Organ Procurement and Transplantation Network (OPTN). Also known as the Charter in these Bylaws.

### OPTN Contractor

The corporation currently operating the OPTN under contract with HHS. In 1984 the National Organ Transplantation Act (NOTA) directed the Secretary of HHS to establish by contract an Organ Procurement and Transplantation Network (OPTN) which shall be a private, non-profit entity that has an expertise in organ procurement and transplantation. The United Network for Organ Sharing (UNOS) is the current OPTN Contractor.

**OPTN Final Rule, see *Final Rule*.**

### OPTN Obligations

Members agree to comply with all OPTN obligations. OPTN obligations include all the applicable provisions of the National Organ Transplant Act (NOTA), OPTN Final Rule, OPTN Charter, OPTN Bylaws, and OPTN Policies.

### OPO Member

A membership category in the OPTN. An OPO member is any organ procurement organization (OPO), as designated by the Secretary of the Department of Health and Human Services (HHS) under *Section 1138(b)* of the Social Security Act or any organization that meets all requirements under *Section 1138(b)* except for OPTN membership. See also *IOPO* and *independent OPO*.

### Organ

A human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."

**Organ Donor, see Donor**

### **Organ Procurement and Transplantation Network (OPTN)**

In 1987, Congress passed the National Organ Transplant Act. The OPTN is the network established as a result of section 372 of that act. The purpose of the OPTN is to improve the effectiveness of the nation's organ procurement, donation and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure. The Act stipulated that the Network be a non-profit, private sector entity comprised of all U.S. transplant hospitals, organ procurement organizations and histocompatibility laboratories. These members, along with professional and voluntary healthcare organizations and the representatives of the general public, are governed by a Board of Directors which reports to the Division of Transplantation, HRSA and the HHS.

**Organ Procurement Organization (OPO) Member, see OPO Member**

## **P**

### **Performance Analysis and Improvement Subcommittee (PAIS)**

A subcommittee of the Membership and Professional Standards Committee charged with reviewing analyzing how a member's actual performance, including post-transplant survival rates and functional activity levels, compares with expected performance.

**Permanent Standing Committees, see Committees.**

### **Plan for Quality Improvement (PQI)**

A Plan for Quality Improvement (PQI) establishes measurable objectives based on priorities identified through the use of established criteria for improving quality and safety of clinical services provided by OPTN members.

### **Policy Compliance Subcommittee (PCSC)**

A subcommittee of the Membership and Professional Standard Committee charged with reviewing a member's compliance with OPTN rules and regulations.

### **Policy Oversight Committee (POC)**

Established by the 2005 OPTN contract, this Committee is charged with reviewing policies (existing and proposed) to assess whether they are helping to meet the goals and metrics set forth by the OPTN Strategic Plan and HRSA's program goals.

### **Potential Candidate**

A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

### **Primary Laboratory Director**

The primary laboratory director is one of the required key personnel that an approved histocompatibility laboratory member must have on site or under contract with the lab.

### **Primary Transplant Physician**

The primary transplant physician is one of the required key personnel that designated transplant programs must have on site. The primary physician must meet the requirements set forth in these Bylaws and is responsible for ensuring the operation and compliance of the program according to the OPTN obligations defined in these Bylaws.

### **Primary Transplant Surgeon**

The primary transplant surgeon is one of the required key personnel that designated transplant programs must have on site. The primary surgeon must meet the requirements set forth in these Bylaws and is responsible for ensuring the operation and compliance of the program according to the OPTN obligations defined in these Bylaws.

### **Program Coverage Plan (PCP)**

The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program. The program director, in conjunction with the primary surgeon and primary physician, must submit a detailed Program Coverage Plan to the OPTN Contractor.

### **Project Officer**

The Project Officer as designated by HRSA for the OPTN Contract.

### **Public Comment**

A pivotal step in the policy making process, public comment assures that the perspectives and concerns of the general public are taken into account and addressed in policy proposals. Generally speaking, the period for public comment is 45 days. The sponsoring Committee creates a public comment document that contains the rationale, the proposal itself and summaries of both. After the document is approved by the Executive Committee, it is distributed to all OPTN members and interested public. The document is mailed to those who request a copy, and an email notification containing a link to the document on the OPTN Web site is sent to the others. Public comment materials are also distributed at regional meetings.

### **Public Organization Member**

A membership category of the OPTN for organizations with an interest in organ donation or transplantation that have been in operation for at least one year.

## **Q**

### **Quorum**

A fixed minimum percentage or number of members of a governing board, committee or organization who must be present before the members can conduct valid business.

## **R**

### **Recipient**

A person who receives a transplant.

## Recovery Hospital

A transplant hospital that performs the surgery to recover living donor organs for transplantation.

## Regional Councillors

Regional councillors are members of the OPTN Board of Directors. Each region elects a regional councillor to represent regional views and opinions to the Board of Directors. Each region determines the guidelines for the election procedures. Councillors and associate councillors serve one to two years and cannot succeed themselves in office. Once elected as a regional councillor, that person's name is added to the ballot for election to the Board of Directors. Since all members of the Board of Directors must be elected by the OPTN membership, regional councillors are included on the ballot and elected to the board in the same manner as the other candidates. The regional councillor provides leadership to the region, facilitating information sharing, mediating differences, conducting regional meetings at least twice yearly, nominating regional representatives to OPTN committees, upholding policies and bylaws, and communicating information affecting transplant practices and policies to the regional membership. See also *councillor*.

## Registration Fee

A fee paid by each transplant hospital members for each transplant candidate listed by that member on the waiting list database maintained by the OPTN Contractor. The OPTN Registration Fee is proposed by the Board of Directors and determined by the Secretary of HHS.

## Review Boards (RRBs)

Peer review panels established in each of the 11 regions to review all urgent status listings for heart candidates. The RRB reviews justification forms submitted by each transplant hospital documenting the severity of the candidate's illness and justifies the status at which the candidate is listed. Heart RRBs review exception requests for heart candidates. These review boards also consider appeals of cases initially refused for a particular medical urgency status.

## Regions

For administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the region in which they are located.

The regions are as follows:

<b>Region 1</b>	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
<b>Region 2</b>	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
<b>Region 3</b>	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
<b>Region 4</b>	Oklahoma, Texas
<b>Region 5</b>	Arizona, California, Nevada, New Mexico, Utah
<b>Region 6</b>	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
<b>Region 7</b>	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
<b>Region 8</b>	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
<b>Region 9</b>	New York, Western Vermont
<b>Region 10</b>	Indiana, Michigan, Ohio
<b>Region 11</b>	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

## S

**SRTR, see Scientific Registry of Transplant Recipients.**

### **Secretary of the U.S. Department of Health and Human Services (HHS)**

The Department of Health and Human Services is the principal agency for protecting the health of all Americans. It is comprised of the Office of the Secretary, who provides leadership for HHS. References to Secretary in these Bylaws refer to the Secretary of HHS or any official of the Department of Health and Human Services designated by the Secretary to have the same authority as the Secretary. See also *Health and Human Services*.

### **Scientific Registry of Transplant Recipients (SRTR)**

The organization that provides ongoing evaluation of clinical data about donors, transplant candidates, and recipients, as well as patient and graft survival rates. The SRTR contract is awarded by HRSA, who oversees and funds it.

Short-term Inactivity

A transplant program that is inactive for no more than 14 consecutive days.

## T

### **Temporary Leave**

When any key personnel take a temporary leave of absence or otherwise temporarily cease their active participation with the transplant hospital, histocompatibility laboratory or OPO. Temporary leave is defined in these Bylaws as greater than 30 days but less than one year.

### **Termination**

When a member's designated transplant program status is terminated by the Secretary of Health and Human Services.

### **Thoracic Organs**

Thoracic organs that can be transplanted include the lungs and heart.

### **Tissue Typing**

A blood test that helps to evaluate how closely the tissues of the donor match those of the recipient.

### **Transplant Hospital Member**

A membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ.

### **Transplant Hospital Patients**

In these Bylaws, Transplant Hospital Patients include *all* of the following:

1. Potential candidates and donors undergoing the hospital's or designated transplant program's evaluation process.
2. Candidates on the waiting list of the hospital or designated transplant program.

3. Potential living donors undergoing the transplant hospital's or designated transplant program's evaluation process and awaiting donation.
4. Living donors being followed by the transplant program.
5. Recipients being followed by the transplant hospital or designated transplant program.

**Transplant Program**, see designated transplant program.

## **U**

**UNOS**, see United Network for Organ Sharing.

### **UNet<sup>SM</sup>**

The secure Internet-based transplant information database created by the United Network for Organ Sharing (UNOS) for the nation's organ transplant institutions to register patients for transplants, match donated organs to transplant candidates, and manage the time-sensitive, life-critical data of both candidates and recipients. UNet<sup>SM</sup> is used by the nation's organ transplant programs, organ procurement organizations (OPOs) and histocompatibility laboratories that work cooperatively to place donated organs safely and equitably.

### **United Network for Organ Sharing (UNOS)**

The private, nonprofit membership organization that coordinates the nation's transplant system through the OPTN Contract. As OPTN Contractor, UNOS is responsible for meeting all contract requirements. UNOS was awarded the first OPTN Contract award in 1986, and has established and continually strives to improve tools, systems and quality processes that support OPTN Contract objectives and requirements.

**U.S. Department of Health and Human Services (HHS)**, see ***Health and Human Services***.

## **V**

### **Vascularized Composite Allograft (VCA)**

A transplant involving any body parts that meets *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation.
2. Containing multiple tissue types.
3. Recovered from a human donor as an anatomical/structural unit.
4. Transplanted into a human recipient as an anatomical/structural unit.
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement).
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7. Not combined with another article such as a device.
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved.
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

## **Voting Members**

References in these Bylaws to *voting members* include those members who have a vote on OPTN business. Voting members are transplant hospital members, independent OPO members (IOPOs), hospital-based OPOs that qualify for voting privileges according to Section 1.3C., independent histocompatibility laboratory members, medical/scientific members, public organization member electors, and individual member electors.

## **W**

### **Waiting List**

The list of candidates registered with the OPTN to receive organ transplants. When a donor organ becomes available, the matching system generates a new, more specific list of potential recipients based on the criteria defined in that organ's allocation policy.

### **Withdrawal**

When a member voluntarily gives up its member status and provides written notice to the OPTN. Members who withdraw from designated transplant program status are voluntarily closing the transplant program.

## **Pending Implementation**

Appendices F.7.E: *Emergency Membership Exceptions for Candidates Less than 18 Years Old* and H.4.E: *Emergency Membership Exceptions for Candidates Less than 18 Years Old*: 12/4/2018 (TBD)

E.5.C: *Conditional Approval for a Pediatric Component*, F.11.A: *Full Intestine Surgeon Approval Pathway*, F.14: *Approved Intestine Surgeon Transplant Fellowship Programs*, J.3.A: *Additional Primary Surgeon Requirements for Upper Limb Transplant Programs*, and J.3.B: *Additional Primary Surgeon Requirements for Head and Neck Transplant Programs*: 12/4/2018 (TBD)

Bylaws Appendix K.5 (Transition Plan during Long-term Inactivity, Termination, or Withdrawal), and Appendix M (Definitions): 12/5/2016 (TBD)

Appendices D.2 (Designated Transplant Program Requirement), D.11.F (Veteran's Administration (VA) Dean's Committee Hospitals), and M (Definitions): 12/5/2016 (TBD)

Appendices D: *Membership Requirements for Transplant Hospital and Transplant Programs* and J: *Membership Requirements for Vascularized Composite Allograft Transplant Programs*: 6/6/2016 (TBD)

Appendices J.A: *Additional Primary Surgeon Requirements for Upper Limb Transplant Programs* and J.B: *Additional Primary Surgeon Requirements for Head and Neck Transplant Programs*: 6/6/2016 (9/1/2018) (Note that this language is not currently reflected in these 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*: 12/2/2015 (TBD)

Appendix F: *Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs*: 6/2/2015 (TBD)

Appendix J: *Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs*: 6/2/2015 (TBD)

**PROOF OF SERVICE OF DOCUMENT**

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I am over the age of 18 and not a party to this bankruptcy case or adversary proceeding. My business address is:

10250 Constellation Blvd., Suite 1700, Los Angeles, CA 90067

A true and correct copy of the foregoing document entitled (*specify*): **SUBMISSION OF SEVENTH REPORT BY PATIENT CARE OMBUDSMAN, JACOB NATHAN RUBIN, MD, FACC, PURSUANT TO 11 U.S.C. § 333(b)(2)** will be served or was served (**a**) on the judge in chambers in the form and manner required by LBR 5005-2(d); and (**b**) in the manner stated below:

**1. TO BE SERVED BY THE COURT VIA NOTICE OF ELECTRONIC FILING (NEF):** Pursuant to controlling General Orders and LBR, the foregoing document will be served by the court via NEF and hyperlink to the document. On (*date*) December 3, 2019, I checked the CM/ECF docket for this bankruptcy case or adversary proceeding and determined that the following persons are on the Electronic Mail Notice List to receive NEF transmission at the email addresses stated below:

Service information continued on attached page

**2. SERVED BY UNITED STATES MAIL:**

On December 3, 2019, I served the following persons and/or entities at the last known addresses in this bankruptcy case or adversary proceeding by placing a true and correct copy thereof in a sealed envelope in the United States mail, first class, postage prepaid, and addressed as follows. Listing the judge here constitutes a declaration that mailing to the judge will be completed no later than 24 hours after the document is filed.

Service information continued on attached page

**3. SERVED BY PERSONAL DELIVERY, OVERNIGHT MAIL, FACSIMILE TRANSMISSION OR EMAIL**

(*state method for each person or entity served*): Pursuant to F.R.Civ.P. 5 and/or controlling LBR, on December 3, 2019, I served the following persons and/or entities by personal delivery, overnight mail service, or (for those who consented in writing to such service method), by facsimile transmission and/or email as follows. Listing the judge here constitutes a declaration that personal delivery on, or overnight mail to, the judge will be completed no later than 24 hours after the document is filed.

Via Attorney Service  
The Honorable Ernest M. Robles  
United States Bankruptcy Court, #1560  
255 E. Temple Street  
Los Angeles, CA 90012

Service information continued on attached page

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

December 3, 2019  
*Date*

Jason Klassi  
*Printed Name*

/s/ Jason Klassi  
*Signature*

**2:18-bk-20151-ER Notice will be electronically mailed to:**

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Alexandra Achamallah on behalf of Creditor Committee Official Committee of Unsecured Creditors of Verity Health System of California, Inc., et al.  
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