

OPTN Organ Procurement and Transplantation Network

Bylaws

Effective Date: December 13, 2012

Contents

ARTICLE I: MEMBERSHIP	1
1.1 MEMBERSHIP GUIDELINES	1
A. <i>Membership Responsibilities</i>	1
B. <i>Overview of the Voting Process</i>	1
C. <i>Meetings</i>	3
D. <i>Expenses</i>	4
E. <i>Member Compliance</i>	4
F. <i>Affiliated Organizations</i>	4
G. <i>Removal of Members</i>	5
1.2 TRANSPLANT HOSPITAL MEMBERS	6
A. <i>Transplant Hospital Member Representatives</i>	6
B. <i>Transplant Hospital Membership Terms</i>	6
C. <i>Transplant Hospital Membership Voting Privileges</i>	6
D. <i>Registration Fees</i>	6
E. <i>Removal of Transplant Hospital Members</i>	7
1.3 OPO MEMBERS	7
A. <i>OPO Member Representatives</i>	7
B. <i>OPO Membership Terms</i>	7
C. <i>OPO Membership Voting Privileges</i>	7
1.4 HISTOCOMPATIBILITY LABORATORY MEMBERS.....	8
A. <i>Histocompatibility Laboratory Member Representatives</i>	8
B. <i>Histocompatibility Laboratory Membership Terms</i>	8
C. <i>Histocompatibility Laboratory Membership Voting Privileges</i>	8
1.5 MEDICAL/SCIENTIFIC MEMBERS	8
A. <i>Medical/Scientific Member Representatives</i>	8
B. <i>Medical/Scientific Membership Terms</i>	9
C. <i>Medical/Scientific Membership Voting Privileges</i>	9
1.6 PUBLIC ORGANIZATION MEMBERS	9
A. <i>Public Organization Member Representatives</i>	9
B. <i>Public Organization Membership Terms</i>	9
C. <i>Public Organization Membership Voting Privileges</i>	9
1.7 BUSINESS MEMBERS	10
A. <i>Business Member Representatives</i>	11
B. <i>Business Membership Terms</i>	11
C. <i>Business Membership Voting Privileges</i>	11
1.8 INDIVIDUAL MEMBERS.....	11
A. <i>Individual Member Representatives</i>	11
B. <i>Individual Membership Terms</i>	11
C. <i>Individual Membership Voting Privileges</i>	12
ARTICLE II: BOARD OF DIRECTORS	13
2.1 COMPOSITION	13

2.2	ELECTION	14
2.3	TERMS	14
2.4	REGIONAL REPRESENTATIVES.....	14
	<i>A. Regional Councillor</i>	15
	<i>B. Associate Councillor</i>	15
	<i>C. Regional Elections</i>	15
	<i>D. Regional Voting Privileges</i>	16
2.5	MEETINGS.....	16
	<i>A. Notice of Meetings</i>	16
	<i>B. Quorum</i>	17
	<i>C. Board Actions</i>	17
	<i>D. Actions without a Meeting</i>	17
2.6	COMMITTEES.....	17
2.7	CONFLICTS OF INTEREST	17
2.8	REMOVAL FROM THE BOARD	18
2.9	RELATIONSHIP OF THE OPTN BOARD AND THE OPTN CONTRACTOR’S BOARD	18
 ARTICLE III: NOMINATING COMMITTEE		19
3.1	COMPOSITION	19
3.2	CONFLICTS OF INTEREST	19
 ARTICLE IV: EXECUTIVE COMMITTEE.....		21
4.1	AUTHORITY	21
4.2	COMPOSITION	21
4.3	SELECTION.....	22
4.4	TERM.....	22
4.5	CONFLICTS OF INTEREST	22
 ARTICLE V: EXECUTIVE DIRECTOR.....		23
5.1	RESPONSIBILITIES	23
5.2	TERM.....	23
5.3	CONFLICTS OF INTEREST	23
 ARTICLE VI: OFFICERS.....		24
6.1	PRESIDENT	24
6.2	VICE PRESIDENT	24
6.3	VICE PRESIDENT OF PATIENT AND DONOR AFFAIRS	24
6.4	TREASURER	24
6.5	SECRETARY	25
6.6	ASSISTANT SECRETARIES	25
6.7	OTHER DUTIES.....	25
6.8	RESIGNATION.....	25
6.9	REMOVAL FROM POSITION	25

6.10	CONFLICTS OF INTEREST	25
ARTICLE VII: PERMANENT STANDING COMMITTEES		26
7.1	COMPOSITION OF STANDING COMMITTEES.....	27
7.2	STANDING COMMITTEE CHAIRS	27
7.3	TERMS OF STANDING COMMITTEE MEMBERS	28
7.4	MEETINGS.....	28
7.5	THE POLICY OVERSIGHT COMMITTEE (POC)	28
	A. <i>Composition of POC</i>	29
	B. <i>Ex-officio Representation</i>	29
	C. <i>POC Chair</i>	29
	D. <i>Terms of POC Members</i>	29
7.6	CONFLICTS OF INTEREST	30
ARTICLE VIII: FISCAL YEAR.....		31
8.1	FISCAL YEAR.....	31
ARTICLE IX: REGIONS		32
9.1	STRUCTURE	32
9.2	MEETINGS.....	32
9.3	REGIONAL REVIEW BOARDS (RRBs).....	33
ARTICLE X: AMENDMENT OF CHARTER AND BYLAWS		34
10.1	VOTING REQUIREMENTS	34
10.2	NOTICE	34
ARTICLE XI: ADOPTION OF POLICIES		35
11.1	CREATING AND SUBMITTING POLICY PROPOSALS.....	35
	A. <i>The Public Comment Period</i>	36
	B. <i>Mandatory and Non-mandatory Policies</i>	36
11.2	SUBMITTING POLICY PROPOSALS TO THE BOARD OF DIRECTORS.....	37
11.3	NOTIFICATION OF POLICY UPDATES.....	38
11.4	ONGOING POLICY REVIEW	38
11.5	ADOPTION OF POLICIES	38
11.6	DEVELOPING ORGAN ALLOCATION POLICIES.....	38
	A. <i>Guidelines for Organ Allocation Policies</i>	38
	B. <i>Organ Allocation Policy Data Analysis</i>	40
APPENDIX A: MEMBERSHIP APPLICATION AND REVIEW.....		41
A.1	GENERAL MEMBERSHIP REQUIREMENTS	41

A.2	DESIGNATED TRANSPLANT PROGRAM REQUIREMENT.....	41
A.3	APPLYING FOR MEMBERSHIP IN THE OPTN	41
	A. <i>Conditions for Application</i>	42
	B. <i>Initial Review of the Membership Application</i>	43
	C. <i>MPSC Review of the Completed Membership Application</i>	44
	D. <i>Final Board of Director’s Review of the Membership Application</i>	45
	E. <i>Processing Time for Membership Applications</i>	46
A.4	RE-APPLICATION AFTER REJECTION FOR MEMBERSHIP.....	46

APPENDIX B: MEMBERSHIP REQUIREMENTS FOR ORGAN PROCUREMENT ORGANIZATIONS (OPOS)..... 47

B.1	OPO COMPLIANCE.....	47
B.2	OPO PERFORMANCE REQUIREMENTS.....	48
B.3	FACILITIES AND SERVICES.....	48
	A. <i>Transplant Hospital Relationship</i>	48
	B. <i>Laboratory Testing Services</i>	49
	C. <i>Tissue Bank Services</i>	49
	D. <i>Education Plans</i>	49
	E. <i>Organ Allocation Plans</i>	49
B.4	OPO PERSONNEL	50
	A. <i>OPO Administrative Director</i>	50
	B. <i>Medical Director</i>	50
	C. <i>Board of Directors</i>	50
	D. <i>Changes in Key Personnel</i>	50
	E. <i>Failure to Report Changes in Key OPO Personnel</i>	50
B.5	ADDITIONAL REQUIREMENTS.....	51
	A. <i>Inactive Status</i>	51
	B. <i>Tax Exemption</i>	51
	C. <i>Fiscal Procedures</i>	51
	D. <i>Medicare Reimbursement</i>	51
	E. <i>Center for Medicare/Medicaid Services (CMS) Certification</i>	51
	F. <i>Donation Service Area</i>	51
	G. <i>Patient Confidentiality</i>	52
	H. <i>Donation after Circulatory Death (DCD) Protocols</i>	52

APPENDIX C: MEMBERSHIP REQUIREMENTS FOR HISTOCOMPATIBILITY LABORATORIES 53

C.1	HISTOCOMPATIBILITY LABORATORY COMPLIANCE	53
C.2	FACILITIES AND RESOURCES.....	53
	A. <i>Size, Lighting, Ventilation and Temperature</i>	53
	B. <i>Refrigeration</i>	53
	C. <i>Liquid Nitrogen Storage</i>	54
	D. <i>Equipment Maintenance</i>	54
	E. <i>Records Storage and Access</i>	54
	F. <i>Health and Safety Compliance</i>	54
	G. <i>Software Validation</i>	54
C.3	HISTOCOMPATIBILITY LABORATORY PERSONNEL.....	54

	A. Laboratory Director.....	55
	B. Technical Supervisor Qualifications and Responsibilities.....	57
	C. General Supervisor	57
	D. Histocompatibility Technologist Qualifications	57
	E. Histocompatibility Technician Qualifications	58
	F. Clinical Consultant Qualifications and Responsibilities.....	58
	G. Competency Testing and Continuing Education of Staff	58
C.4	CHANGES IN KEY LABORATORY PERSONNEL.....	59
C.5	HISTOCOMPATIBILITY LABORATORY POLICIES AND PROCEDURES.....	59
	A. Criteria for Mandatory Performance Review of Director, Technical Supervisor or Clinical Consultant	59
	B. Information Required from Laboratories with Unsatisfactory Performance	60
	C. Periodic Reviews.....	61
	D. Regulatory Agency Adverse Actions.....	61
	E. Inactive Status.....	61
C.6	HISTOCOMPATIBILITY LABORATORY TESTING REQUIREMENTS.....	61
	A. Handling of Specimens	61
	B. Handling of Reagents.....	62
	C. Testing Standards	62
	D. Quality Assurance	64
	E. Procedure Manual.....	64
	F. Records and Test Reports	64
	G. Service Requirements.....	66
	H. Subcontracting	66
	I. Submission Requirements for New Laboratories.....	66
	J. Submission Requirements for Laboratories Using New Techniques.....	67

APPENDIX D: MEMBERSHIP REQUIREMENTS FOR TRANSPLANT HOSPITALS AND TRANSPLANT PROGRAMS..... 69

D.1	TRANSPLANT HOSPITAL COMPLIANCE.....	69
D.2	DESIGNATED TRANSPLANT PROGRAM REQUIREMENT.....	69
D.3	FACILITIES AND RESOURCES.....	70
	A. Facilities.....	70
	B. OPO Affiliation.....	70
	C. Histocompatibility Laboratory Affiliation	70
	D. Blood Bank Services	70
	E. Additional Laboratory Services	70
D.4	TRANSPLANT PROGRAM DIRECTOR	70
D.5	TRANSPLANT PROGRAM KEY PERSONNEL	71
	A. Primary Transplant Surgeon and Physician.....	71
	B. Surgeon and Physician Coverage (Program Coverage Plan)	72
	C. Surgeons and Physicians Designated as Primary Transplant Surgeon or Physician before July 1, 2006.....	73
D.6	CHANGES IN KEY TRANSPLANT PROGRAM PERSONNEL.....	73
	A. Primary Surgeon or Primary Physician Departure	74
	B. Primary Surgeon or Primary Physician Change in Role	74
	C. Primary Surgeon or Primary Physician Temporary Leave.....	75

	D. Reinstatement of Previously Designated Primary Surgeon or Primary Physician.....	75
	E. Failure to Notify the OPTN Contractor of Key Personnel Changes	76
	F. Processing Applications for Changes to Key Personnel.....	76
D.7	OTHER TRANSPLANT PROGRAM PERSONNEL	77
	A. Clinical Transplant Coordinator.....	77
	B. Financial Coordinator	78
	C. Clinical Transplant Pharmacist.....	79
	D. Medical Expert Support.....	79
	E. Mental Health and Social Support.....	79
D.8	INVESTIGATION OF TRANSPLANT PERSONNEL	80
D.9	REVIEW OF TRANSPLANT PROGRAM FUNCTIONAL ACTIVITY	80
	A. Functional Inactivity.....	80
	B. Requirements of Functional Inactivity	81
D.10	ADDITIONAL TRANSPLANT PROGRAM REQUIREMENTS	82
	A. Transplant Program Survival Rates	82
	B. Routine Referral Procedures.....	83
	C. Candidate Selection Procedures.....	83
	D. Donation after Circulatory Death (DCD) Protocols	83
	E. Veteran’s Administration (VA) Dean’s Committee Hospitals	83
	F. Relocation or Transfer of Designated Transplant Programs.....	83

APPENDIX E: MEMBERSHIP AND PERSONNEL REQUIREMENTS FOR KIDNEY TRANSPLANT PROGRAMS..... 85

E.1	PROGRAM DIRECTOR, PRIMARY TRANSPLANT SURGEON AND PRIMARY TRANSPLANT PHYSICIAN.....	85
E.2	PRIMARY KIDNEY TRANSPLANT SURGEON REQUIREMENTS.....	85
	A. Formal 2-year Transplant Fellowship Pathway.....	86
	B. Clinical Experience Pathway.....	87
	C. Alternative Pathway for Predominantly Pediatric Programs	88
E.3	PRIMARY KIDNEY TRANSPLANT PHYSICIAN REQUIREMENTS.....	89
	A. Twelve-month Transplant Nephrology Fellowship Pathway	90
	B. Clinical Experience Pathway.....	91
	C. Three-year Pediatric Nephrology Fellowship Pathway	92
	D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway	94
	E. Combined Pediatric Nephrology Training and Experience Pathway	95
	F. Alternative Pathway for Predominantly Pediatric Programs	97
	G. Conditional Approval for Primary Transplant Physician.....	98
E.4	APPROVED KIDNEY TRANSPLANT SURGEON AND PHYSICIAN FELLOWSHIP TRAINING PROGRAMS	100
	A. Transplant Surgeon Fellowship Training Programs.....	100
	B. Transplant Physician Fellowship Training Programs.....	100
E.5	KIDNEY TRANSPLANT PROGRAMS THAT PERFORM LIVING DONOR RECOVERY	101
	A. Potential Living Donor Medical Evaluation.....	102
	B. Psychological Assessments.....	102
	C. Independent Donor Advocate	102
	D. Primary Open Living Donor Kidney Surgeon	102
	E. Primary Laparoscopic Living Donor Kidney Surgeon	103
	F. Kidney Paired Donation.....	103
	G. Required Living Donor Protocols	103

APPENDIX F: MEMBERSHIP AND PERSONNEL REQUIREMENTS FOR LIVER TRANSPLANT PROGRAMS 104

F.1	PROGRAM DIRECTOR, PRIMARY TRANSPLANT SURGEON AND PRIMARY TRANSPLANT PHYSICIAN....	104
F.2	PRIMARY LIVER TRANSPLANT SURGEON REQUIREMENTS	104
	A. <i>Formal 2-year Transplant Fellowship Pathway</i>	105
	B. <i>Clinical Experience Pathway</i>	106
	C. <i>Alternative Pathway for Predominantly Pediatric Programs</i>	107
F.3	PRIMARY LIVER TRANSPLANT PHYSICIAN REQUIREMENTS	108
	A. <i>12-month Transplant Hepatology Fellowship Pathway</i>	109
	B. <i>Clinical Experience Pathway</i>	110
	C. <i>Three-year Pediatric Gastroenterology Fellowship Pathway</i>	111
	D. <i>Pediatric Transplant Hepatology Fellowship Pathway</i>	113
	E. <i>Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway</i>	114
	F. <i>Alternative Pathway for Predominantly Pediatric Programs</i>	116
	G. <i>Conditional Approval for Primary Transplant Physician</i>	117
F.4	REQUIREMENTS FOR DIRECTOR OF LIVER TRANSPLANT ANESTHESIA.....	119
	A. <i>Director of Liver Transplant Anesthesia Administrative Responsibilities</i>	119
	B. <i>Required Policies for Anesthesiology Participation</i>	119
	C. <i>Director of Liver Transplant Anesthesia Clinical Responsibilities</i>	119
	D. <i>Director of Liver Transplant Anesthesia Qualifications</i>	120
F.5	APPROVED LIVER SURGEON TRANSPLANT FELLOWSHIP PROGRAMS.....	120
F.6	LIVER TRANSPLANT PROGRAMS THAT PERFORM LIVING DONOR RECOVERY	121
	A. <i>Living Donor Surgeon Requirements</i>	121
	B. <i>Potential Living Donor Medical Evaluations</i>	121
	C. <i>Potential Living Donor Psychological Assessments</i>	121
	D. <i>Independent Donor Advocate</i>	121
	E. <i>Conditional Program Approval Status</i>	122

APPENDIX G: MEMBERSHIP AND PERSONNEL REQUIREMENTS FOR PANCREAS AND PANCREATIC ISLET TRANSPLANT PROGRAMS 124

G.1	PANCREAS PROGRAM DIRECTOR, PRIMARY TRANSPLANT SURGEON AND PRIMARY TRANSPLANT PHYSICIAN.....	124
G.2	PRIMARY PANCREAS TRANSPLANT SURGEON REQUIREMENTS.....	124
	A. <i>Formal 2-year Transplant Fellowship Pathway</i>	125
	B. <i>Clinical Experience Pathway</i>	126
	C. <i>Alternate Pathway for Predominantly Pediatric Programs</i>	127
G.3	PRIMARY PANCREAS TRANSPLANT PHYSICIAN REQUIREMENTS.....	128
	A. <i>Twelve-month Transplant Medicine Fellowship Pathway</i>	129
	B. <i>Clinical Experience Pathway</i>	130
	C. <i>Alternative Pathway for Predominantly Pediatric Programs</i>	131
	D. <i>Conditional Approval for Primary Transplant Physician</i>	132
G.4	REQUIREMENTS FOR DESIGNATED PANCREATIC ISLET TRANSPLANT PROGRAMS.....	134
	A. <i>Reporting</i>	134
	B. <i>Transplant Facilities</i>	135
	C. <i>Expert Medical Personnel</i>	135
	D. <i>Islet Isolation</i>	135

	<i>E. Programs Not Located at an Approved Pancreas Transplant Program</i>	135
G.5	PRIMARY PANCREATIC ISLET TRANSPLANT SURGEON REQUIREMENTS.....	136
G.6	PRIMARY PANCREATIC ISLET TRANSPLANT PHYSICIAN REQUIREMENTS.....	136
G.7	APPROVED PANCREAS TRANSPLANT SURGEON FELLOWSHIP TRAINING PROGRAMS	136

APPENDIX H: MEMBERSHIP AND PERSONNEL REQUIREMENTS FOR HEART TRANSPLANT PROGRAMS 137

H.1	PROGRAM DIRECTOR, PRIMARY TRANSPLANT SURGEON, AND PRIMARY TRANSPLANT PHYSICIAN...	137
H.2	PRIMARY HEART TRANSPLANT SURGEON REQUIREMENTS.....	137
	<i>A. Cardiothoracic Surgery Residency Pathway</i>	138
	<i>B. Twelve-month Heart Transplant Fellowship Pathway</i>	139
	<i>C. Clinical Experience Pathway</i>	140
	<i>D. Alternative Pathway for Predominantly Pediatric Programs</i>	141
H.3	PRIMARY HEART TRANSPLANT PHYSICIAN REQUIREMENTS.....	142
	<i>A. Twelve-month Transplant Cardiology Fellowship Pathway</i>	142
	<i>B. Clinical Experience Pathway</i>	143
	<i>C. Alternative Pathway for Predominantly Pediatric Programs</i>	145
	<i>D. Conditional Approval for Primary Transplant Physician</i>	145

APPENDIX I: MEMBERSHIP AND PERSONNEL REQUIREMENTS FOR LUNG TRANSPLANT PROGRAMS 148

I.1	PROGRAM DIRECTOR, PRIMARY TRANSPLANT SURGEON, AND PRIMARY TRANSPLANT PHYSICIAN...	148
I.2	PRIMARY LUNG TRANSPLANT SURGEON REQUIREMENTS	148
	<i>A. Cardiothoracic Surgery Residency Pathway</i>	149
	<i>B. Twelve-month Lung Transplant Fellowship Pathway</i>	150
	<i>C. Clinical Experience Pathway</i>	151
	<i>D. Alternative Pathway for Predominantly Pediatric Programs</i>	152
I.3	PRIMARY LUNG TRANSPLANT PHYSICIAN REQUIREMENTS.....	153
	<i>A. Twelve-month Transplant Pulmonary Fellowship Pathway</i>	154
	<i>B. Clinical Experience Pathway</i>	155
	<i>C. Alternative Pathway for Predominantly Pediatric Programs</i>	156
	<i>D. Conditional Approval for Primary Transplant Physician</i>	157

APPENDIX J: MEMBERSHIP AND PERSONNEL REQUIREMENTS FOR JOINT HEART AND LUNG PROGRAMS 159

J.1	PROGRAM DIRECTOR, PRIMARY TRANSPLANT SURGEON, AND PRIMARY TRANSPLANT PHYSICIAN...	159
J.2	PRIMARY HEART AND LUNG TRANSPLANT SURGEON REQUIREMENTS	159
J.3	PRIMARY HEART AND LUNG TRANSPLANT PHYSICIAN	159

APPENDIX K: TRANSPLANT PROGRAM INACTIVITY, WITHDRAWAL, AND TERMINATION. 160

K.1	TRANSPLANT PROGRAM INACTIVITY.....	160
K.2	SHORT-TERM INACTIVE TRANSPLANT PROGRAM STATUS.....	160
	<i>A. Notice to Patients</i>	160

K.3	LONG-TERM INACTIVE TRANSPLANT PROGRAM STATUS.....	161
	A. <i>Notice to the OPTN Contractor of Long-term Inactive Status</i>	161
	B. <i>Notice to the Patients of Long-term Inactive Status</i>	161
	C. <i>Reactivation after Voluntary Long-term Inactive Status</i>	162
	D. <i>Extension of Voluntary Long-term Inactive Status</i>	162
K.4	WITHDRAWAL OR TERMINATION OF DESIGNATED TRANSPLANT PROGRAM STATUS	162
	A. <i>Notice to the OPTN Contractor</i>	162
	B. <i>Notice to the Patients</i>	163
K.5	TRANSITION PLAN DURING LONG-TERM INACTIVITY, TERMINATION, OR WITHDRAWAL.....	163
K.6	TRANSFERRED CANDIDATES WAITING TIME	165
K.7	LABORATORY TESTS.....	165

APPENDIX L: REVIEWS, ACTIONS, AND DUE PROCESS..... 166

L.1.	MEMBER COMPLIANCE.....	166
	A. <i>Periodic Reviews</i>	166
	B. <i>Failure to Pay OPTN Fees</i>	166
L.2.	COMPLIANCE MONITORING.....	166
L.3.	REPORTING POTENTIAL VIOLATIONS AND NON-COMPLIANCE.....	166
L.4.	METHODS FOR CORRESPONDENCE AND PROVIDING NOTICE.....	167
L.5.	MEDICAL PEER REVIEW	167
	A. <i>Secretary's Access to Information</i>	167
	B. <i>Health Resources and Services Administration (HRSA) Representation</i>	168
L.6.	REQUESTS FOR ROOT CAUSE ANALYSIS AND CORRECTIVE ACTION	168
	A. <i>Initiating Corrective Action</i>	168
	B. <i>Fulfilling Requests for Root Cause Analysis and Corrective Action</i>	168
L.7.	SPECIAL SECRETARIAL REVIEWS.....	168
L.8.	REVIEW PATHWAYS FOR POTENTIAL VIOLATIONS	169
L.9.	PRELIMINARY INVESTIGATION OF POTENTIAL VIOLATIONS	169
	A. <i>Referral of Potential Violations to the MPSC Chair</i>	170
	B. <i>Notice to the Secretary after Preliminary Investigation</i>	170
L.10.	DETERMINATION OF REVIEW PATHWAY.....	170
	A. <i>MPSC Chair's Determination of Urgency and Severity</i>	170
	B. <i>Requests to Take Action to Mitigate Imminent Threat</i>	170
	C. <i>Notice of Chair's Determination</i>	171
	D. <i>Changing Review Pathways</i>	171
L.11.	OPTN INVESTIGATIONS	171
L.12.	IMMINENT THREAT REVIEWS	171
	A. <i>Imminent Threat Review Investigation</i>	171
	B. <i>Imminent Threat Review Committee</i>	171
	C. <i>Interviews in Imminent Threat Reviews</i>	172
	D. <i>OPTN Executive Committee Determination</i>	172
	E. <i>Notice after OPTN Executive Committee's Determination</i>	173
	F. <i>Requesting a Hearing in Imminent Threat Reviews</i>	173
	G. <i>Imminent Threat Hearing Process</i>	173
L.13.	EXPEDITED REVIEWS.....	174
	A. <i>Expedited Review Investigation</i>	174
	B. <i>Expedited Review Committee</i>	174

	C. <i>Interviews in Expedited Reviews</i>	175
	D. <i>Requesting a Hearing in Expedited Reviews</i>	175
	E. <i>Expedited Review Hearing Panel</i>	175
	F. <i>Expedited Review Hearing Process</i>	176
L.14.	ROUTINE REVIEWS.....	176
	A. <i>Routine Review Investigations</i>	176
	B. <i>Routine Review Committee</i>	176
	C. <i>Interviews in Routine Reviews</i>	176
	D. <i>Hearings in Routine Reviews</i>	177
L.15.	OPTN DETERMINATIONS AND ACTIONS.....	177
	A. <i>Determining Appropriate Action</i>	178
	B. <i>Corrective Action</i>	178
	C. <i>Deferred Disposition with Monitoring Period</i>	179
	D. <i>MPSC Actions without Board Referral</i>	180
	E. <i>Adverse Actions that Require Board Approval</i>	181
	F. <i>Recommendations and Requests to the Secretary</i>	183
L.16.	SECRETARIAL ACTIONS.....	183
	A. <i>OPTN Policies Approved by the Secretary as Mandatory</i>	184
L.17.	INTERVIEWS.....	185
	A. <i>Members' Right to an Interview</i>	185
	B. <i>Requesting an Interview</i>	185
	C. <i>Notice of Interview</i>	185
	D. <i>Notice to Member after an Interview</i>	186
	E. <i>Informal Discussion</i>	186
L.18.	HEARINGS.....	186
	A. <i>Members' Right to a Hearing</i>	186
	B. <i>Requesting a Hearing</i>	187
	C. <i>Notice of Hearing</i>	187
	D. <i>Appointment of Hearing Panels</i>	187
	E. <i>Hearing Participants</i>	188
	F. <i>Service on Hearing Panels</i>	188
	G. <i>Appearance and Representation at Hearings</i>	188
	H. <i>Presiding Officer</i>	188
	I. <i>Rights of Hearing Participants</i>	188
	J. <i>Procedure and Evidence</i>	189
	K. <i>Official Notice</i>	189
	L. <i>Burden of Proof</i>	189
	M. <i>Hearing Record</i>	190
	N. <i>Postponement</i>	190
	O. <i>Presence of Hearing Panel</i>	190
	P. <i>Recesses and Adjournment</i>	190
	Q. <i>Action after Hearing</i>	190
	R. <i>Hearing Panel Report</i>	191
	S. <i>Notice after Hearing</i>	191
	T. <i>Effect of Favorable Result</i>	191
	U. <i>Effect of Adverse Result</i>	191
L.19.	FINAL DECISION OF THE BOARD OF DIRECTORS.....	191
	A. <i>Right to Appear before the Board</i>	191
	B. <i>Board of Directors Action</i>	192

	C. <i>Notice</i>	193
L.20.	RESTORATION OF UNRESTRICTED MEMBERSHIP PRIVILEGES.....	193
	A. <i>Request for Restoration of Membership Privileges</i>	193
	B. <i>Minimum Requirements to Request Restoration of Membership Privileges</i>	194
	C. <i>Additional Requirements</i>	194
	D. <i>Hearing</i>	194
	E. <i>Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule</i>	194
L.21.	LESSER ADVERSE ACTIONS	195
	A. <i>Requesting a Lesser Adverse Action</i>	195
	B. <i>Considering Requests for Lesser Adverse Actions</i>	195
L.22.	REJECTED MEMBERSHIP APPLICATIONS	196
L.23.	COSTS AND EXPENSES	196
	A. <i>Reimbursement of OPTN Contractor Costs and Expenses</i>	196
	B. <i>Reasonable Costs and Expenses</i>	197
	C. <i>Advanced Deposit for Reimbursable Costs and Expenses</i>	197
	D. <i>Default in Payment of Reimbursable Cost and Expenses</i>	198
	APPENDIX M: DEFINITIONS	199

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 Guidelines

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:

Membership Type	Number of Votes	Additional Requirements to Qualify for Voting Rights
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, as defined in <i>Section 1.3</i> .
Histocompatibility laboratory	One per histocompatibility laboratory	The histocompatibility laboratory must be independent, as defined in <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 can only vote once on each resolution.

OPTN business that requires a vote of the membership may include election of the Board of Directors (see *Article II: Board of Directors*), election of the officers (see *Article VI: Officers*), and amendment of these Bylaws (see *Article X: Amendment of Charter and Bylaws*).

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 applicable provisions of the:

1. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*
2. OPTN Final Rule, 42 CFR Part 121
3. OPTN Bylaws
4. OPTN Policies

The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital, histocompatibility, and OPO member for compliance with the OPTN Final Rule, OPTN Bylaws and OPTN Policies. All OPTN members are monitored for compliance with the OPTN Final Rule, OPTN Bylaws and OPTN Policies. All compliance monitoring is performed using guidelines developed by the OPTN Contractor. Any member who no longer qualifies as an OPTN member according to the requirements of these Bylaws will be dealt with according to *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

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 be acting in a way that poses a risk to the health or safety of patients or the public.

F. 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.

G. Removal of Members

Transplant hospital members who no longer qualify as an OPTN member will be treated according to *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

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 sixty (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 sixty (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, Actions, and Due Process* of these Bylaws.

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 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.

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.
- 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 list 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 treated according to *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

1.3 OPO Members

An OPO member is any organ procurement organization (OPO), as designated by the Secretary of the 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.

A. OPO Member Representatives

Independent 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 OPO member has one vote, provided that the OPO is independent. An independent OPO (IOPO) is defined for this purpose as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

1.4 Histocompatibility Laboratory Members

A histocompatibility laboratory member is any histocompatibility laboratory that serves at least one transplant hospital within its service area.

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 <http://optn.transplant.hrsa.gov>, 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 <http://optn.transplant.hrsa.gov>, 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 Directors. Provided that at least one nomination is received from each category, the Directors will represent the following categories:

- Transplant physicians and surgeons. Approximately 50 percent of the 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 gender and racial diversity of this population.
- Individuals representing voluntary health organizations.
- Pediatric specialists. At least one Director must represent pediatric interests.
- 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 automatically a member of the Board.

The Project Officer for the OPTN Contract and the Director of the Division of Transplantation (DoT) of the U.S. Department of Health and Human Services (HSS), or a representative they designate, serve *ex-officio* and do not have a vote on the Board of Directors.

2.2 Election

Directors of the OPTN Board are elected by majority vote of members with voting privileges. The members vote, either in person or by proxy, at the annual meeting when a quorum is present. 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 voting member has only one vote for each Director position.

The officers will be elected by the voting members, not by the Directors. The treasurer and the vice president of Patient & Donor Affairs are elected in odd-numbered years. The Secretary is elected in even-numbered years. For more information, see *Article VI: Officers*.

2.3 Terms

Directors will serve for a term of two years, with exceptions as noted below. Terms begin on July 1 following the election of the Board of Directors.

These 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 vote to extend the term of any of these Directors for one year. A Director's term may not be extended more than two times.

The treasurer, Secretary and the vice president of patient and donor affairs serve two-year terms. All other officers serve one-year terms.

2.4 Regional Representatives

There are 11 identified OPTN geographic regions in the United States. For more information about the OPTN regions, see *Article IX: Regions* of these Bylaws. Each OPTN region elects a councillor and associate councillor through a vote of its members with voting privileges.

A. Regional Councillor

The councillor serves as the region’s representative on the Board of Directors. Each region determines the guidelines for the electing councillors. 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.

Regional councillors are included on the national ballot of candidates for Board of Directors. Members then elect the regional councillors at the annual meeting to serve for two-year terms that begin July 1 following the election. Councillors cannot serve consecutive terms as councillors.

A councillor may be removed from the Board of Directors for any reason by majority vote of the region's members, member electors, and individuals with voting privileges. The majority vote must be supported by signed ballots presented to the president or the Board of Directors.

B. Associate Councillor

Each region determines the guidelines for electing associate councillors. The associate councillor represents the region on the Membership and Professional Standards Committee (MPSC). If the councillor is absent from a Board of Directors meeting, the associate councillor may represent the region and act in place of the councillor, but the associate councillor does not have a vote.

Associate councillors serve on the MPSC for a two -year term that begins July 1 following the election. Associate councillors cannot serve consecutive terms as associate councillors.

C. Regional Elections

Regional elections will be completed on or before December 31 of each year, unless otherwise directed by the Board of Directors or the president. The current councillor, after consultation with or a vote of the region’s members, will select one of the following regional election processes:

- An election with one slate for councillor and a second slate for associate councillor. The subsequent elections will include only a slate for a new associate councillor, with the current associate councillor automatically becoming the councillor.
- An election with one slate of nominees for councillor and a second slate for the associate councillor
- An election with a single slate of nominees for councillor. The person who receives the most votes is the councillor and the person who receives the second highest number of votes will be associate councillor.

In all these cases, the slate will be composed of nominations submitted by members, member electors, and individuals with voting privileges.

D. 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.

Others who have regional voting privileges may include:

- Any interested 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.
- Representatives of medical/scientific members with principal offices located in a region, as determined by guidelines developed by the region.

2.5 Meetings

Regular meetings of the Board of Directors are held at least twice each calendar year at a location selected by the Executive Director. One of these meetings is held in the Washington, D.C. metropolitan area, which includes Richmond, VA. The Board may call other regular or special meetings as it considers necessary. Meetings of Directors may be held in person or by any communication method that enables all Directors to both listen and speak to one another throughout the meeting.

OPTN Board meetings are open to the public. However, the Board of Directors will 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. 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 included in closed sessions of OPTN meetings.

A. Notice of Meetings

Written notice of any regular or special meeting of the Board of Directors must include the date, time and place of the meeting. The notice must be provided to each Director at the address provided to the Executive Director not more than 60 days or fewer than 10 days before the date of the meeting. The Executive Director must also distribute the agenda for each Board of Directors meeting at least 10 days before the meeting, to allow input from the members.

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 Directors eligible to vote constitute a quorum for transacting business at any meeting of the Board.

C. Board Actions

When a quorum is achieved, a majority vote of the 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 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 Directors. In order for actions to be taken without a meeting, all Directors must vote on the action and the vote must be unanimous.

2.6 Committees

The Permanent Standing Committees of the OPTN are defined in *Article VII: Permanent Standing Committees* of these Bylaws. The Board may periodically establish and then dissolve ad hoc committees for specific purposes, finite functions, or limited periods of time.

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 Removal from the Board

A Director may be removed from office for any reason, but only by the voting members and member electors at a meeting convened specifically to remove the Director. For more information about meetings of members, see *Article I: Membership* of these Bylaws.

2.9 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. The Board of Directors will consider the recommendations of the Nominating Committee and may make changes before attaching its final list of nominees to the notice of the annual meeting, or any special meeting called to elect officers and Directors.

3.1 Composition

The Nominating Committee is appointed by the president and will have no more than 12 voting members. 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:

- Regional councillors
- Heart Transplant Representative
- 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 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. The 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 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

Officers are elected at the annual meeting of members and begin their terms on July 1. Officers serve on the Board without compensation, and may only hold one position on the Board at a time.

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.

6.1 President

The president will preside at all meetings of the members and Directors. The president serves for a term of one year, and may not serve consecutive terms.

6.2 Vice President

The vice president is the president-elect of the OPTN and serves as Chair 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. The vice president serves for a term of one year, and may not serve consecutive terms.

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. The vice president of patient and donor affairs serves for a term of two years and is elected in odd-numbered years. The vice president of patient and donor affairs may serve consecutive terms.

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. The treasurer serves a two-year term and is elected in odd-numbered years.

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. The secretary serves a two-year term and is elected in even-numbered years.

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 in writing at any time to the Executive Director. The Board of Directors will elect a successor at its next meeting to serve until its next annual meeting of Members.

6.9 Removal from Position

An officer may be removed for any reason at any regular or special meeting of the Board of Directors at which a quorum is present. Removal must be by a vote of two-thirds of the Directors present. The Board of Directors will elect a successor to a removed officer to serve until the next annual meeting of the members.

Assistant treasurers and assistant secretaries may be removed by the Board of Directors or the Executive Committee for any reason.

6.10 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
- Finance
- 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 Standing Committee 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 and the vice president serves as the Chair of the Membership and Professional Standards Committee (MPSC). The vice president, with approval of the Board of Directors, appoints the Chair of the other standing Committees.

Chairs of the standing Committees have the following terms:

- The vice president serves a one-year term as the Chair of the MPSC.

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

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.

7.3 Terms of Standing Committee Members

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

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

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 as a permanent standing committee the Policy Oversight Committee (POC). The POC will be advisory to the Board of Directors. The POC will also:

- Provide written recommendations about policies to the Board of Directors at least twice a year.
- Review and comment on research projects being conducted and published by the OPTN and the Scientific Registry of Transplant Recipients (SRTR).

- Work in collaboration with the SRTR Technical Advisory Committee (STAC) to identify and develop SRTR research priorities.

A. Composition of POC

The POC will be comprised of the Vice Chairs of the organ-related and constituency Committees and the following other members:

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

B. Ex-officio Representation

The Policy Oversight Committee will also have 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.

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

C. POC Chair

The president, with approval of the Board of Directors, will appoint for two year terms the Chair of the POC. POC Chairs may be appointed to consecutive terms.

D. Terms of POC Members

With the exception of the MPSC Vice Chair, all standing Committee Vice Chairs serve *ex-officio* on the Policy Oversight Committee. All other members of the POC serve for terms of two years. POC terms begin on July 1.

7.6 Conflicts of Interest

All OPTN standing 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.

- Organ Procurement and Transplantation Network (OPTN) Bylaws

Article VIII: Fiscal Year

8.1 Fiscal Year

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

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 Review Boards (RRBs)

Each region establishes regional review boards (RRBs) for specific organs as necessary. RRBs 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, RRBs 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.

RRBs are formed for each region under the direction of the Committees and Board of Directors. RRBs can operate and perform peer review functions as determined by the Board of Directors and considering issues that affect their region. The Board of Directors and Committees may establish other guidelines for RRB organization and function as necessary.

Voting members of the RRBs include physicians and surgeons who are active in organ transplantation from each transplant program in the region for the relevant organ. Regions with a large number of transplant hospitals may use a rotation schedule for physician and surgeon representation on RRBs. A rotation schedule lets transplant hospitals alternate assigning representatives to the RRB so that each transplant hospital is given an equal opportunity to serve on the RRB.

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.

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 require immediate action due to patient health and safety factors.
- 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. The sponsoring Committee may set a shorter period if a proposal needs to be expedited for patient health and safety reasons, but will make every effort to set a reasonable period to receive comments.

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

1. Posted to the OPTN website at <http://optn.transplant.hrsa.gov> 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 UNetsm 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, <http://optn.transplant.hrsa.gov>.

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 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.

11.6 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.

A.1 General Membership Requirements

To become a member and maintain membership status in the OPTN, organizations and individuals must do *all* of the following:

1. Complete the OPTN membership application process.
2. Consistently meet all OPTN obligations established by the OPTN Board of Directors.
3. Comply with the OPTN Charter, Bylaws, and Policies.

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

A.2 Designated Transplant Program Requirement

Every transplant hospital member must have current approval as a designated transplant program for at least one organ. A transplant hospital can receive approval as a designated transplant program for one or more organs through the application process described in this *Appendix A*. Transplant hospitals must complete separate applications for each organ-specific designated transplant program at the hospital.

A.3 Applying for Membership in the OPTN

The Membership and Professional Standards Committee (MPSC) reviews each application for membership under confidential medical peer review and makes recommendations for approval or rejection of the application to the Board of Directors.

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. Hearings and appellate reviews
 - iv. 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.

Interim MPSC Rejection of the Membership Application

Any applicant rejected for membership by the MPSC may request due process. For more information about the due process options available after a membership rejection, see *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. If it is going to do so, the applicant must exercise its due process rights before the adverse recommendation is submitted to the Board of Directors by the MPSC.

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.

A recommendation for rejection by the Board of Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The applicant may also make a written appeal to the Secretary within 30 days of the final rejection of the application by the Board of Directors.

E. Processing Time for Membership Applications

The MPSC or an MPSC subcommittee will act on an application and provide a recommendation for interim approval or rejection within 90 days after the OPTN Contractor receives the completed application. Applications for membership and designated transplant program approval will be considered in a timely and good faith manner by the OPTN and the OPTN Contractor and, except for good cause, will be processed within the 90-day period.

A.4 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)**

An OPO member is any OPO that has been designated by the Secretary of the U.S. 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.

Only independent OPOs (IOPO) have voting privileges in the OPTN. An IOPO is defined as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

A hospital-based OPO is not independent from the transplant hospital it serves. Hospital-based OPOs are held to the same standards and requirements as OPO members, but do not have a vote on OPTN business separate from the vote granted the transplant hospital member that controls it.

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

B.1 OPO Compliance

By accepting membership in the OPTN, OPOs agree to comply with all applicable provisions of the:

1. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*
2. OPTN Final Rule, 42 CFR Part 121
3. OPTN Bylaws
4. OPTN Policies

The OPTN will conduct ongoing periodic reviews and on-site evaluations of each OPO for compliance with the OPTN Final Rule, OPTN Bylaws and OPTN Policies. OPOs must also fulfill all requests for information from the OPTN Contractor as required to determine compliance. All compliance monitoring is performed using procedures developed by the OPTN Contractor. Any OPO that no longer qualifies as an OPTN member according to the requirements of these Bylaws will be dealt with according to *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

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. The evaluation may include a peer visit to the OPO at the OPO's expense.

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. A difference of at least 11.
2. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10).
3. A ratio of observed to expected yield less than 0.90, 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 do so will constitute a violation of OPTN obligations.

B.3 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. Failure to comply with these requirements could result in corrective action as described in *Appendix L: Reviews, Actions, and Due Process* of these

Bylaws, if applicable, or result in a recommendation to the Board of Directors to notify the Secretary of HHS.

B.4 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

Failure to inform the OPTN Contractor of changes in the administrative director or medical director may result in corrective action as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws, including adverse actions as defined in *L.15. OPTN Determinations 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.5 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 2.0: Minimum Procurement Standards for an Organ Procurement Organization (OPO)*. These protocols must be made available to the OPTN Contractor on request.

Appendix C: Membership Requirements for Histocompatibility Laboratories

A histocompatibility laboratory member is any histocompatibility laboratory that serves at least one transplant hospital within its Donation Service Area (DSA).

An independent histocompatibility laboratory has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves. Only independent histocompatibility laboratories have voting privileges in the OPTN. For more information on the terms, voting privileges, and responsibilities of histocompatibility laboratories, see *Article I: Membership* of these Bylaws.

C.1 Histocompatibility Laboratory Compliance

By accepting membership in the OPTN, each histocompatibility member agrees to comply with all applicable provisions of the:

1. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.
2. OPTN Final Rule, 42 CFR Part 121
3. OPTN Bylaws
4. OPTN Policies

C.2 Facilities and Resources

Histocompatibility laboratories require considerable facilities and resources to ensure accurate, reliable and efficient testing. The following sections describe the minimum required facilities and resources required for a histocompatibility laboratory.

A. Size, Lighting, Ventilation and Temperature

The laboratory must have:

1. Enough space so that procedures and tests can be performed accurately and efficiently.
2. Adequate lighting and ventilation.
3. The proper temperature as specified in the laboratory's procedure manual so that procedures are completed in the optimal temperature range.

B. Refrigeration

Refrigerators and freezers must be monitored to ensure the optimal storage temperature for samples and reagents. Refrigerators and freezers must be equipped with an audible or centrally located temperature alarm system. If a

refrigerator or freezer fails, an emergency storage plan must be in place and followed.

C. Liquid Nitrogen Storage

If liquid nitrogen is used for storage of frozen cells, the liquid nitrogen level in the freezers must be monitored to ensure an adequate supply at all times.

D. Equipment Maintenance

The laboratory must establish and adhere to policies and procedures for the proper maintenance of equipment, instruments and test systems by:

1. Defining and performing the preventive maintenance program for each instrument and piece of equipment.
2. Performing and documenting function checks on equipment with at least the frequency specified by the manufacturer.
3. Verifying that the equipment is calibrated at least every six months.

E. Records Storage and Access

The laboratory must have adequate facilities to store medical and test records. Records must be available onsite for at least two years and readily accessible after that for at least the period specified by local, state and federal regulations.

F. Health and Safety Compliance

The laboratory must comply with all applicable federal, state and local health and safety regulations including:

1. Fire safety regulations.
2. Regulations for the storage, handling and disposal of hazardous chemical, biological and radioactive materials.

G. Software Validation

The laboratory must have documented validation of all software used for patient data analysis to ensure that computer-assisted analyses are accurate.

C.3 Histocompatibility Laboratory Personnel

The laboratory must employ a director, a technical supervisor, and a clinical consultant. One person may fill one, two, or all three positions.

The size and training of the 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. These personnel requirements are consistent with the current Clinical Laboratory Improvement

Act (CLIA) regulations, which outline the requirements for all histocompatibility laboratories.

A. Laboratory Director

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

Laboratory Director Qualifications

The laboratory director must meet *all* of the following requirements:

1. The director must be an M.D., D.O., or Ph.D. in science, and must meet the qualifications of a director of high complexity testing according to federal CLIA requirements defined in *42CFR §493.1441*. An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located.
2. The director must have at least two years training or experience in histocompatibility testing in an OPTN approved training program or three years experience under an OPTN histocompatibility laboratory director.

Laboratory Director Candidate Requirements

Any professional being considered for the position of laboratory director must also provide *one* of the following:

- Proof of certification by the American Board of Histocompatibility and Immunogenetics.
- A portfolio of cases covered during training in an OPTN approved transplant hospital. If a portfolio is submitted, the portfolio may be also reviewed by an OPTN approved accrediting agency as part of their application process. The portfolio must include:
 1. A log of 50 cases reviewed in each histocompatibility testing technique used in organ transplantation. Each case should include the date and a record identification number, along with a brief description and the testing technology used. A minimum of ten of these cases must include all the related worksheets and notes.
 2. Cases that demonstrate the applicant’s analytical skills, including the ability to recognize and resolve difficult testing and interpretation issues. These cases should also include instances when the applicant made recommendations for additional testing or clinical care.

In addition, laboratories must submit the following items as part of the application:

1. Proof of active laboratory interaction with transplant professionals.

2. A letter that describes all experience in immunology and clinical histocompatibility testing.
3. A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.
4. A current curriculum vitae or resume.
5. A demonstrated knowledge of the fundamentals of immunology, genetics, and histocompatibility testing and this knowledge should be reflected by participation in professional conferences and publications in peer reviewed journals. An American Board of Histocompatibility and Immunogenetics Diplomat (ABHI D) certification is highly recommended.

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.

Laboratory Director Responsibilities

A histocompatibility laboratory director has the following responsibilities:

1. Ensure that the laboratory facilities are adequate and safe from physical, chemical, and biological hazards.
2. Provide consultation to clients on test results.
3. Be available to provide onsite, telephone or electronic consultation, as needed.
4. Ensure that an approved procedure manual is available to all technical personnel.
5. Supervise personnel to ensure that all duties are properly performed.
6. Ensure that a qualified General Supervisor is on-site for all testing.
7. Ensure that there are current job descriptions and task assignments for all personnel.
8. Ensure that the performance of personnel is evaluated and documented at least semi-annually during the first year, and annually after that.
9. Be available to all staff members to address issues of concern.
10. Ensure that test systems provide quality results.
11. Ensure that the laboratory enrolls in appropriate proficiency testing programs.
12. Ensure that the laboratory has quality control and quality assurance programs.
13. Ensure that corrective action is taken if test systems deviate from performance specifications.
14. Ensure all required information is included on test reports.
15. Employ enough staff with appropriate training and experience.

Laboratories must document if any of the director's responsibilities will be performed by other Laboratory staff. This documentation must include a list of the duties delegated, the times when these 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.

B. Technical Supervisor Qualifications and Responsibilities

The technical supervisor must meet all the qualifications for laboratory director as outlined in *C.3.A. Laboratory Director* above and for technical supervisor as specified in *42CFR493*. In addition, the supervisor must have at least two years of training in an OPTN approved training program or three years experience under a qualified OPTN histocompatibility laboratory director.

A technical supervisor has the following responsibilities:

1. Select appropriate test methodologies.
2. Establish performance criteria, validation, and quality control for all tests.
3. Ensure proficiency testing is performed properly and reviewed with staff.
4. Ensure that technical problems are resolved and corrective action is taken when appropriate.
5. Ensure that test reports are issued only when test systems are functioning properly.
6. Identify training needs and provide in-service training as needed.
7. Evaluate staff competency and performance.

Laboratories must document any technical supervisor responsibilities that will be delegated, including a list of the duties delegated, the times when these duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure each duty is correctly performed.

C. General Supervisor

A general supervisor must have *one* of the following:

- A bachelor’s degree and at least three years experience in human histocompatibility or transplant immunology testing under the supervision of a qualified director or technical supervisor.
- A related associate’s degree or certificate, as required by CLIA, and five years of supervised experience if a bachelor’s degree has not been earned. A Certified Histocompatibility Specialist (CHS ABHI) certification is strongly recommended.

D. Histocompatibility Technologist Qualifications

A histocompatibility technologist must meet the qualifications for a histocompatibility technologist as defined by CLIA 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. Either CHS ABHI or Certified Histocompatibility Technologist (CHT ABHI) certification is strongly recommended.

E. Histocompatibility Technician Qualifications

The term histocompatibility technician is applied to trainees and other laboratory personnel with less than one year’s supervised experience in human histocompatibility or transplantation immunology testing, regardless of academic degree or other training and experience.

F. Clinical Consultant Qualifications and Responsibilities

A qualified clinical consultant must be available to consult with and provide opinions about the appropriateness of histocompatibility or transplantation immunology tests ordered. The clinical consultant will interpret test results in consideration of patient diagnosis and management. Required qualifications are described in detail in the final version of the CLIA Regulations.

The clinical consultant must be an M.D., D.O. or Ph.D. in science. An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located. A Ph.D. must be board-certified by an accrediting agency accepted by the U.S. Department of Health and Human Services (HHS). The clinical consultant must also have experience in clinical transplantation.

A histocompatibility laboratory clinical consultant has the following responsibilities:

1. Ensure that test reports include all information required for test interpretation.
2. Ensure that consultation is available at all times to evaluate patient and donor compatibility for organ transplantation and that availability is communicated with laboratory clients.
3. Assist clients in test selection.
4. Assist clients in the interpretation of reported test results.
5. Report assessed risks associated with the degree and specificity of allosensitization and crossmatch results.

G. 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 Changes in Key Laboratory Personnel

To maintain a histocompatibility laboratory's OPTN membership approval, the laboratory must have a qualified director, technical supervisor and clinical consultant on staff at all times. When the laboratory learns that a director, technical supervisor or clinical consultant plans to leave, it must notify the OPTN contractor immediately, within 30 days if possible, of departure. At this time, the laboratory must submit to the OPTN Contractor the name of the replacement, curriculum vitae, and information required for compliance with OPTN criteria for histocompatibility laboratory membership.

Failure to inform the OPTN Contractor of changes in key personnel may result in disciplinary action as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

C.5 Histocompatibility Laboratory Policies and Procedures

The overall performance of a laboratory is the best indication of the quality of leadership, technical supervision, and clinical consultation being provided. The sections below describe the areas that are monitored and assessed by the OPTN Histocompatibility Committee or the accrediting agencies approved by the OPTN Contractor, and are used to measure the laboratory's performance.

A. Criteria for Mandatory Performance Review of Director, Technical Supervisor or Clinical Consultant

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

- Less than 100% successful performance in an ABO external proficiency testing program.
- For programs other than ABO, a less than 80% successful performance in an external proficiency testing program within a year.
- 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.

A histocompatibility laboratory will also be reviewed if it has *two or more* of the following performance indicators annually:

- Error rates not within acceptable limits as defined by the laboratory quality assurance program.
- Test completion times that are not within acceptable limits as defined by the laboratory quality assurance program.
- Incomplete or missing proof of training, continuing education, and competency evaluations for all personnel as required by the OPTN Contractor.
- Incomplete or missing records of all continuing education for testing staff, director, technical supervisor or clinical consultant.
- Incomplete or missing documentation of annual director review of training and competency evaluation for all testing staff.
- Deficiencies 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.
- Significant discrepancies in deceased donor HLA typing results.

B. Information Required from Laboratories with Unsatisfactory Performance

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

- Letters from transplant program physicians or coordinators describing the level of interaction and involvement of the director, technical supervisor and clinical consultant.
- Interviews with transplant program 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 extracurricular commitments, including estimates of time required, for director, technical consultant and clinical consultant outside of the histocompatibility laboratory. This may include other employment, current committee assignments, teaching commitments, students mentored, research commitments, grants, and all other patient care responsibilities.
- Other material as requested.

C. Periodic Reviews

In order to determine compliance with the OPTN Final Rule, *42 CFR Part 121*, these Bylaws, and OPTN Policy, histocompatibility laboratory members will be reviewed, including on-site reviews, and must fulfill any requests for information from the OPTN Contractor. Failure to comply with these rules and requirements will be cause for corrective action as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

D. Regulatory Agency Adverse Actions

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

E. 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.6 Histocompatibility Laboratory Testing Requirements

The laboratory must perform tests only at the written or electronic request of an authorized person. The laboratory must ensure that the request includes:

1. The test subject's name or other unique identifier.
2. The name and address or other identification of the person who ordered the test.
3. Date of specimen collection.
4. Time of specimen collection, if significant to the test.
5. Tests ordered.

Oral requests for laboratory tests are permitted only if the laboratory obtains written authorization for testing within 30 days of the request.

A. Handling of Specimens

Histocompatibility laboratories must have available and follow written policies and procedures for specimen collection. Laboratories must follow these guidelines when handling and processing specimens for testing:

1. Each blood or tissue sample submitted for testing must be individually labeled with the name or other unique identification number for the individual and the date of collection.

2. The laboratory must maintain a system to ensure reliable specimen identification throughout collection, processing, testing and reporting. The laboratory must have criteria for specimen rejection and a process to ensure that rejected specimens are not tested.
3. If the laboratory draws blood samples, it must use a procedure that ensures minimal possibility of infection of the donor and contamination of the sample. All needles and syringes must be disposable.
4. Laboratory personnel must handle and transport all blood and tissue samples as though they could transmit infectious diseases.
5. The laboratory must confirm and document that anticoagulant and preservation solutions do not interfere with test performance. The anticoagulant or preservation solutions used must preserve the specimen integrity for the length of time and under the storage conditions the laboratory procedures require between sample collection and testing.

B. Handling of Reagents

The laboratory must properly label and store all reagents according to manufacturer's instructions or regulatory agency requirements to maintain optimal reactivity and specificity. Any deviation from a manufacturer's instructions for storage or any local storage guidelines must be explained by the laboratory.

Reagents, solutions, culture media, controls, calibrators, and other supplies must be labeled to indicate:

1. Identity including titer, strength or concentration.
2. Recommended storage requirements.
3. Preparation and expiration date, if any.

Laboratories must have a policy for quality control of each shipment and lot of reagents, and must adhere to the policy. Laboratories must ensure that:

1. Reagents from different lots of commercial kits are not mixed.
2. A process is in place to document the lot of reagents used in tests.
3. Each new shipment and lot of reagent is tested for quality and performance before test results using these reagents are reported.

C. Testing Standards

Laboratories must meet requirements for testing accuracy and completeness as established by the OPTN Board of Directors through the OPTN Contractor policy development process. These standards are established to ensure accurate and dependable histocompatibility testing consistent with current technology and the availability of reagents. These testing standards establish minimal criteria that all histocompatibility laboratories must meet.

The following testing standards have been prepared by the Histocompatibility Committee, and approved by the OPTN Board of Directors:

1. All procedures used in histocompatibility testing must conform to established protocols and be independently validated by the laboratory prior to use for clinical testing.
2. Each procedure must include quality assurance measures to monitor test performance.
3. Laboratories using its approval by the OPTN Contractor as proof of compliance to these standards must be current OPTN members.

The laboratory must perform at least twice a year a side-by-side comparison of any test results if it:

1. Performs the same test using different methods or instruments.
2. Performs the same test at multiple sites.

The laboratory must verify or establish for each testing method the performance requirements for accuracy, precision, analytical sensitivity and specificity, and the acceptable range of test results. The laboratory must have appropriate controls for each test to evaluate test performance and accuracy.

Proficiency Testing and Competency Evaluation

The laboratory must participate in at least one external proficiency testing program, if available, for each analyte to assess the laboratory's ability to accurately perform testing. If an external proficiency program is not available, the laboratory must use other procedures that meet CLIA requirements to validate performance at least semi-annually for each analyte. The laboratory must test proficiency samples in the same manner as that for testing clinical samples.

The laboratory must determine and document the cause for each unsatisfactory proficiency test result. Unsatisfactory performance can be *either* of the following:

- Less than 80 percent correct for an entire year for a specific analyte or within a single survey.
- Two out of three consecutive surveys graded as unsatisfactory.

If a laboratory's performance in an external proficiency testing program is unsatisfactory, the laboratory must participate in an enhanced proficiency testing program until given a satisfactory result.

D. Quality Assurance

Laboratories must have ongoing procedures for monitoring and evaluating its quality assurance program including procedures to evaluate corrective action taken. Laboratories must document and assess problems identified during quality assurance reviews, discuss them with the staff, and take corrective action to prevent recurrences. Ineffective policies and procedures must be revised based on the outcome of the evaluation.

Laboratories must document all quality assurance activities including problems identified and corrective action taken, for a minimum of two years or the period required by local, state, federal and OPTN regulations.

If any error or discrepancies in test results are detected, the laboratory must promptly:

1. Notify the person ordering or using the test results.
2. Issue corrected results and reports.
3. Maintain copies of both the original and the corrected report for a minimum of two years or the period required by local, state and federal regulations.

Laboratories must also have a process for addressing any discrepancies in HLA typing results for the same individual as reported by different laboratories or at different times as described in *OPTN Policy, Appendix 3C*.

E. Procedure Manual

All laboratory procedures must be detailed in a procedure manual that is readily available and located where the procedures are performed. Manufacturer product inserts are not acceptable in place of a written procedure.

The Laboratory Director must review the procedure manual at least annually and document this review in the manual. The Director must approve any new procedures or changes in existing procedures and record this approval in the manual by signing and dating the manual when the changes are made.

F. Records and Test Reports

The laboratory must record the following information for each test performed:

1. Test requisition.
2. Subject identification number.
3. Accession number or unique identification of the specimen.
4. The tissue source of the specimen.
5. The dates of specimen collection and receipt.
6. The time of specimen receipt, if relevant.

7. The condition and disposal of the specimens that do not meet the criteria for acceptability.
8. The records and dates for specimen testing including the staff that performed the tests.
9. The tests, the type of specimen used for testing, test data and results.
10. Copies of preliminary and final reports, including dates.
11. Documented review of these by the Director or Technical Supervisor or other staff member who meets at least the minimum requirements of General Supervisor.

The laboratory must have record storage systems that enable it to report results in a timely, accurate, reliable and confidential manner. Records may be saved in computer files provided that back-up files (either electronic or hard copies) are maintained to prevent loss of data.

The laboratory must ensure test subject confidentiality throughout the parts of the testing process that are under the laboratory's control.

All test reports must contain:

1. The name and address or other unique identifier of the laboratory or institution.
2. The date of sample collection.
3. The date of sample testing when pertinent to the interpretation of the test.
4. The name or unique identifier of each individual tested.
5. The date of the report.
6. The test results.
7. The units of measurement, if applicable.

Reports must be reviewed by the Director or Technical Supervisor or a staff member who meets at least the minimum requirements of a General Supervisor prior to release. All deceased donor HLA typing or crossmatch reports must be reviewed during the next day of regular laboratory operation.

Waiting List Data Verification

All histocompatibility laboratories must review and verify the Waiting List histocompatibility data for every patient whose test results the laboratory completed. Documentation of such review must be kept for at least three years or the period required by local, state and federal regulations, whichever is the longer. This document must be available to the OPTN Contractor on request.

G. Service Requirements

All complaints and problems reported to any laboratory must be documented. The Laboratory must investigate complaints and take corrective action as necessary.

The laboratory must have a system in place to document problems that result from communications failures between the laboratory and the individual who orders tests or receives results.

The laboratory must, upon request, make available to clients a list of the test methods employed by the laboratory, a list of performance specifications for each method and a list of interfering factors that could affect interpretation of test results. Updates on testing information must be provided whenever changes occur that affect test results or the interpretation of test results.

H. Subcontracting

A histocompatibility laboratory may use another laboratory as a subcontractor to perform testing. If a histocompatibility laboratory refers testing to another laboratory, the subcontracting laboratory must be *both*:

1. CLIA certified or exempt.
2. OPTN-approved, ASHI accredited, or CAP accredited for that testing.

For all testing performed by a subcontractor laboratory, the results must be returned to the referring laboratory and released only after the review and approval of the Director of the laboratory. 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.

Proficiency testing must not be referred to another laboratory.

I. Submission Requirements for New Laboratories

A new histocompatibility laboratory is defined as one that has not yet been approved as an OPTN histocompatibility laboratory member.

New laboratories are required to submit procedures and test validation data for all categories and methods of testing unless the testing is performed, without exception, by another approved laboratory. These materials must be submitted to an OPTN approved histocompatibility laboratory accrediting agency.

J. Submission Requirements for Laboratories Using New Techniques

A new technique is defined as a major change or addition in testing methodology, including but not limited to:

- The addition of molecular typing for class I or class II.
- A major addition or change in the method used for molecular typing.
- The addition of flow cytometry phenotyping or crossmatching.
- A major addition or change in the method used for antibody identification or crossmatching.

Laboratories adding or changing test methods must submit procedures and test validation data for the new tests and methods to an OPTN approved histocompatibility laboratory accrediting agency, with a copy to the OPTN Histocompatibility Committee. The laboratory must also submit the curriculum vitae for the Director documenting experience in the new testing.

The curriculum vitae should include qualifications such as publications and years of experience as the Director of another laboratory approved for the new techniques. A summary of the Director review of five cases for each type of test, including the testing and interpretation, may be submitted instead if the Director does not have documented experience in the new techniques.

The following data are required when a histocompatibility laboratory begins using a new testing technique:

1. A summary of the internal validation data and the Director's summary of that data.
2. The step-by-step procedure including worksheets and list of reagents.
3. The clinical protocol that validates the use of the procedure.
4. The program for training staff in the new testing technique.
5. Documentation of the training of staff that will be performing the test and reviewing the test results.
6. Performance requirements, including accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, and any other relevant characteristics.
7. Quality control procedures.
8. Calibration data for necessary equipment.
9. Quality assurance data.
10. Evidence that the laboratory is currently enrolled in a Proficiency Testing (PT) program for the test, if available.
11. Tests results including worksheets and sample reports with interpretation of 10 samples including at least one of each of the test materials that will be used by the laboratory. Laboratories without access to a particular type of

- sample may request that it be supplied by another OPTN accredited laboratory. Multiple samples from the same individual may not be used.
12. Externally blinded side-by-side validation tests using specimens from an OPTN accredited laboratory, or well-characterized reference materials (ASHI repository or commercial panels) equivalent to those provided by the selected PT program, or a complete year of PT. A combination of these may also be used to meet this requirement.

Results from the reference laboratory and the validating laboratory must be reported independently.

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.

D.1 Transplant Hospital Compliance

Transplant hospital members agree to:

1. Review and abide by the OPTN Final Rule, Bylaws, Policies and applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*
2. Comply with all obligations of OPTN membership.
3. Submit to reviews and on-site evaluations to monitor compliance with membership requirements.
4. Fulfill all requests for information.
5. Notify the OPTN Contractor within 10 business days if any regulatory agency takes a final adverse action against the transplant hospital and then provide any documents relating to the final adverse action to the OPTN Contractor.

For more information, see *Article I: Membership* of these Bylaws.

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.

D.3 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.4 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.5.B. Surgeon and Physician Coverage (Program Coverage Plan)* in this appendix for more information on the Program Coverage Plan.

D.5 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*
- *Appendix J: Membership and Personnel Requirements for Joint Heart and Lung 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.6 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.5.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

Any member who fails to inform the OPTN Contractor of a change in the primary surgeon or primary physician or to submit the required Personnel Change Application within the periods specified above will be reviewed by the MPSC. The MPSC may impose a sanction, including *any* of the following:

- A Notice of Uncontested Violation
- Letter of Warning
- Letter of Reprimand

Each of these sanctions and other adverse actions that may be taken by the MPSC are further described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

Failure to inform the OPTN Contractor of changes in primary surgeon or primary physician or to submit the required Personnel Change Application will result in a recommendation that the Board of Directors take appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of Health and Human Services (HHS) of the violation.

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.

D.7 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.8 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.

Failure to comply with these requirements will result in a recommendation to the Board of Directors to notify the Secretary, or a recommendation to take appropriate action according to *Appendix L: Reviews, Actions, and Due Process* these Bylaws.

D.9 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active. Transplant program functional activity 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. For purposes of these Bylaws, functional inactivity is defined as *any* of the following:

1. The inability to serve potential candidates, candidates, or recipients for a period of 15 or more consecutive days.
2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.
3. The failure to perform a transplant during the periods defined in the table below:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

Given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements for functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

B. Requirements of Functional Inactivity

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

1. Inactivates its waiting list or is unable to perform transplants for 15 or more consecutive days.
2. Inactivates its waiting list or is unable to perform transplants for 28 or more cumulative days over any 365 consecutive day period.

The MPSC may also require, at its discretion, that the member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC.

The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to 12 months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than 12 months, the member should relinquish designated transplant program status as required in these Bylaws.

The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's inactivity.

D.10 Additional Transplant Program Requirements

A. Transplant Program Survival Rates

The MPSC will review a transplant program if it has a low survival rate compared to the expected survival rate for that transplant program. The review will be to determine if the low survival rate can be explained by patient mix or some other unique clinical aspect of the transplant program. The MPSC may conduct a peer visit to the program at member expense and may require the member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the member participate in an informal discussion.

The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

While the precise statistical criteria may be selected by the MPSC, the initial criteria used to identify programs with low patient or graft survival rates will include *all* of the following:

1. The finding that *observed events* minus *expected events* is greater than 3.
2. The finding that the *observed events* divided by *expected events* is greater than 1.5.
3. There exists a one-sided *p value* less than 0.05.

Observed events are deaths or graft losses as reported in UNETsm database. *Expected events* are deaths or graft losses as calculated using organ-specific transplant models.

Those programs whose actual observed patient or graft survival rates fall below their expected rates by more than a 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, subject to Board approval.

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to do so will constitute a violation of OPTN membership requirements.

B. 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.

C. Candidate Selection Procedures

Each transplant program must establish procedures for selecting transplant candidates and distributing organs efficiently and equitably.

D. 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 *OPTN Policy 2.0*.

E. 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.

F. 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.5.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 foreign equivalent. In the case of a surgeon who has just completed training and whose board certification in urology is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 12 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 12-month period.

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

- The formal 2-year transplant fellowship pathway, as described in *Section E.2.A. Formal 2-year Transplant Fellowship Pathway* below.
- The kidney transplant program clinical experience pathway, as described in *Section E.2.B. Clinical Experience Pathway* below.

A. Formal 2-year Transplant Fellowship Pathway

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

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant over the 2-year period. At least 3 of these procurements must be multiple organ procurements and at least 10 must be from deceased donors. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects

of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

4. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
 - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

B. Clinical Experience Pathway

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

1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated kidney transplant program, or its foreign equivalent. The transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.

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

C. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary kidney transplant surgeon through either the transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections E.2.A or E.2.B* above.

2. The surgeon has maintained a current working knowledge of all aspects of kidney transplantation and patient care, defined as direct involvement in kidney transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board of Directors.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

E.3 Primary Kidney Transplant Physician Requirements

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 foreign equivalent.

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

- The 12-month transplant nephrology fellowship pathway, as described in *Section E.3.A. Twelve-month Transplant Nephrology Fellowship Pathway* below.
- The clinical experience pathway, as described in *Section E.3.B. Clinical Experience Pathway* below.
- The 3-year pediatric nephrology fellowship pathway, as described in *Section E.3.C. Three-year Pediatric Nephrology Fellowship Pathway* below.
- The 12-month pediatric transplant nephrology fellowship pathway, as described in *Section E.3.D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway* below.
- The combined pediatric nephrology training and experience pathway, as described in *Section E.3.E. Combined Pediatric Nephrology Training and Experience Pathway* below.

A. Twelve-month Transplant Nephrology Fellowship Pathway

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

1. The physician has current board certification in nephrology by the American Board of Internal Medicine or the foreign equivalent.
2. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
3. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor

selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).

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

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

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct

supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a Kidney transplant program or the foreign equivalent. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.

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

C. Three-year Pediatric Nephrology Fellowship Pathway

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency

Review Committee for Pediatrics (RRC-Ped) of the ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the following conditions must be met:

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

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

D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

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

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another Kidney transplant program in order to meet these requirements. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
3. The experience in caring for pediatric patients occurred at a kidney transplant program with a qualified kidney transplant physician and surgeon that performs an average of at least 10 pediatric kidney transplants a year.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients

for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

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

E. Combined Pediatric Nephrology Training and Experience Pathway

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

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.

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

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

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

F. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections E.3.A through E.3.E* above.
2. The physician has maintained a current working knowledge of all aspects of kidney transplantation, defined as direct involvement in kidney transplant patient care within the last 2 years.
3. The physician receives a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

G. Conditional Approval for Primary Transplant Physician

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

1. The physician has current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 23 or more newly transplanted kidney recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
4. The physician has 12 months experience on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician should have observed at least 3 organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another kidney transplant program.

7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
 - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

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

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

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

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 2-year formal transplant fellowship must complete their training at a fellowship program approved by the MPSC. Any program approved for training by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program that meets the following criteria:

1. The program is at a hospital that transplants one or more organs, including kidneys.
2. The program is at an institution that has a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary kidney transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.
6. The program performs at least 60 kidney transplants each year from deceased or living donors.
7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new program.

B. Transplant Physician Fellowship Training Programs

A formal training program for primary kidney transplant physicians requires that training must be completed at a program approved by the MPSC. Any training program approved by the AST/ASN Adult Renal Transplant Training Accreditation Program is automatically accepted by the MPSC, as well as any program that meets the following criteria:

1. The program must be OPTN approved as a kidney transplant program and be affiliated with an ACGME approved nephrology program. Transplant programs that are not OPTN approved or affiliated with an ACGME approved nephrology program will be evaluated on a case-by-case basis.

2. The program must perform at least 10 kidney transplants per year for each first year, general nephrology fellow in training and an additional 30 transplants per year for each kidney transplant fellow to be trained.
3. The program must have a full-time faculty member or members capable of teaching a curriculum with a broad base of knowledge in transplant medicine. The 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. Combined surgical and medical rounds should be conducted on a regular basis.
4. 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. The transplant renal fellow must be primarily responsible for 30 in-patient renal transplant recipients and 30 outpatient recipients over a period of 12 months. Outpatient follow-up must be continuous for a minimum of at least 3 months. Training must be completed within 12 continuous months; a minimum of 6 months of training must be performed in inpatient clinical service.
5. The transplant nephrology fellow must perform a minimum of 10 transplant biopsies during the training period.
6. The transplant nephrology fellow must observe at least 3 kidney transplants and at least 3 procurement procedures.

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. Potential Living Donor Medical Evaluation

The kidney recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor.

B. Psychological Assessments

The kidney recovery hospital must have the clinical resources to perform a psychosocial assessment of the potential donor’s ability to make an informed decision. This psychosocial assessment should also confirm that the evaluation and donation are completely voluntary.

C. Independent Donor Advocate

The kidney recovery hospital must have an Independent Donor Advocate (IDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the potential living donor. The IDA must be independent of the decision to transplant the potential recipient and follow the Protocols that outline the duties and responsibilities of the IDA as described in *OPTN Policy 12.0*.

The goals of the IDA are:

- To promote the best interests of the potential living donor.
- To advocate the rights of the potential living donor.
- To assist the potential living donor in obtaining and understanding information about the consent process, evaluation process, surgical procedure, as well as the benefit of and need for follow-up care.

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 an accredited American Society of Transplant Surgeons (ASTS) fellowship with kidney certification.
- Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon or First Assistant. 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 or first assistant. Seven of these nephrectomies must have been performed as the primary surgeon, and this role should be documented by a letter from the fellowship program director. 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

Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.

G. Required Living Donor Protocols

Kidney recovery hospitals must develop protocols that address:

1. The living donation process
2. Duties for the Independent Donor Advocate (IDA)
3. Medical evaluations
4. Informed consent

The requirements for these protocols are described in detail in *OPTN Policy 12.0*.

Appendix F: Membership and Personnel Requirements for Liver 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.1 Program Director, Primary Transplant Surgeon and Primary 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.5.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

F.2 Primary Liver Transplant Surgeon Requirements

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

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

3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification in urology is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 12 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 12-month period.

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

- The formal 2-year transplant fellowship pathway, as described in *Section F.2.A. Formal 2-year Transplant Fellowship Pathway* below.
- The liver transplant program clinical experience pathway, as described in *Section F.2.B. Clinical Experience Pathway* below.

A. Formal 2-year Transplant Fellowship Pathway

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

1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant during the 2-year period. At least 3 of these procurements must include selection and management of the donor. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and

complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

4. The training was completed at a hospital with a transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in *Section F.5 Approved Liver Surgeon Transplant Fellowship Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
 - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details his or her training and experience in liver transplantation.

B. Clinical Experience Pathway

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

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

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

C. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary liver transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.2.A or F.2.B* above.
2. The surgeon has maintained a current working knowledge of all aspects of liver transplantation and patient care, defined as direct involvement in liver transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or

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

4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

F.3 Primary Liver Transplant Physician Requirements

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

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

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

- The 12-month transplant hepatology fellowship pathway, as described in *Section F.3.A. 12-month Transplant Hepatology Fellowship Pathway* below.

- The clinical experience pathway, as described in *Section F.3.B. Clinical Experience Pathway* below.
- The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.3.C. Three-year Pediatric Gastroenterology Fellowship Pathway* below.
- The 12-month pediatric transplant hepatology fellowship pathway, as described in *Section F.3.D. Pediatric Transplant Hepatology Fellowship Pathway* below.
- 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.

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

A. 12-month Transplant Hepatology Fellowship Pathway

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

1. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program. The training must have included at least 3 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted liver recipients, and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing,

immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

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

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

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 50 or more newly transplanted liver recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program or the foreign equivalent. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by

the program director, division chief, or department chair from the program where the physician gained this experience.

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

C. Three-year Pediatric Gastroenterology Fellowship Pathway

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

1. The physician has current board certification in gastroenterology by the American Board of Pediatrics, or the foreign equivalent.

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

requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.

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

D. Pediatric Transplant Hepatology Fellowship Pathway

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

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

tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.

5. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation, the donation process, and the care of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor and Donor ID.
6. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
 - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

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

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

1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.

2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and along with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver 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 should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation of donor, the donation process, and the management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
 - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's

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

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

F. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.3.A through F.3.E* above.
2. The physician has maintained a current working knowledge of all aspects of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

G. Conditional Approval for Primary Transplant Physician

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

1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program, or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50

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

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

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

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

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

F.4 Requirements for Director of Liver Transplant Anesthesia

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

The director of liver transplant anesthesia must be a Diplomate of the American Board of Anesthesiology, or the foreign equivalent.

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.5 Approved Liver Surgeon Transplant Fellowship Programs

Surgeons qualifying as primary transplant surgeon based on completion of a 2-year formal transplant fellowship must complete their training at a fellowship program approved by the MPSC. Any program approved for training by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program that meets the following criteria:

1. The program is at a hospital that transplants one or more organs, including livers.
2. The program is at an institution that has a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary liver transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.
6. The program performs at least 50 liver transplants each year from deceased or living donors.
7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new program.

F.6 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 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. Seven of these procedures must have been live donor procedures. 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. Potential 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 potential living donor.

C. Potential Living Donor Psychological Assessments

This liver recovery hospital must have the clinical resources to perform psychosocial assessment of the potential living donor's ability to make an informed decision. This psychosocial assessment should also reinforce and confirm that the evaluation and donation are completely voluntary.

D. Independent Donor Advocate

The liver recovery hospital must have an independent donor advocate (IDA) who is not involved with the evaluation or treatment decisions of the potential recipient, is independent of the decision to transplant the potential recipient, and is a knowledgeable advocate for the potential living donor.

The goals of the IDA are:

- To promote the best interests of the potential living donor.
- To advocate the rights of the potential living donor.
- To assist the potential living donor in obtaining and understanding information about the consent process, the evaluation process, and the surgical procedure.
- To explain the benefits of and need for follow-up care.

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 2-year conditional approval period, it must stop performing living donor liver recoveries by *either*:

1. Inactivating the living donor component of the program for a period up to 12 months.
2. Relinquishing the living donor component of the liver transplant program until it can meet the requirements for full approval.

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.5.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 foreign equivalent. In the case of a surgeon who has just completed training and whose board certification in urology is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 12 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 12-month period.

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

- The formal 2-year transplant fellowship pathway, as described in *Section G.2.A. Formal 2-year Transplant Fellowship Pathway* below.
- The pancreas transplant program clinical experience pathway, as described in *Section G.2.B. Clinical Experience Pathway* below.

A. Formal 2-year Transplant Fellowship Pathway

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

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

complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.

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

B. Clinical Experience Pathway

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

1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon or first assistant, at a designated pancreas transplant program or its foreign equivalent. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.

2. The surgeon has performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a pancreas transplant program.
 - b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the individual, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

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.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

G.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 foreign equivalent.

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

- The 12-month pancreas transplant fellowship pathway, as described in *Section G.3.A. Twelve-month Transplant Medicine Fellowship Pathway* below.
- The clinical experience pathway, as described in *Section G.3.B. Clinical Experience Pathway* below.

A. Twelve-month Transplant Medicine Fellowship Pathway

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

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

5. The curriculum of this transplant medicine fellowship should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
6. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
 - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program that the physician previously served, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a pancreas transplant program, or its foreign equivalent. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive

therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.

3. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The physician should have also observed the evaluation of the donor, the donation process, and the management of at least 3 multiple organ donors who donated a pancreas. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
 - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program the physician previously served, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

D. Conditional Approval for Primary Transplant Physician

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

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.

3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or its foreign equivalent. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a pancreas. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.
7. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
 - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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

conditional approval period ends 12 months after the first approval date of the personnel change application.

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

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

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.E. 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. Reporting

The program must submit data to the OPTN Contractor for all donors, potential transplant recipients, and actual transplant recipients using the required forms.

Pending development of standardized data forms for pancreatic islet transplantation, the program must maintain patient logs and provide them to the OPTN Contractor every 6 months. The patient logs must be cumulative and must include for each transplant performed:

1. The patient name
2. Social security number
3. Date of birth
4. Donor ID
5. Patient status (alive or dead)
6. Whether the pancreas was allocated for islet or whole organ transplantation

For each pancreas allocated to the program for islet transplantation, the program must report to the OPTN Contractor if the islets were used for transplantation. If the islets were not used in transplantation, the program must report the reason

and disposal method, together with other information requested on the Pancreatic Islet Donor Form.

B. 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.

C. 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.

D. 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.

E. 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

Fellowship training programs accredited by the Fellowship Training Committee of the American Society of Transplant Surgeons are acceptable to the OPTN Contractor or all programs that meet the following criteria:

1. The program must be located at a hospital that transplants one or more organs.
2. The program must be reviewed every 5 years by the OPTN Contractor.
3. The program must be at an institution with a proven commitment to graduate medical education.
4. The program director must be a board certified surgeon who meets the requirements of a primary transplant surgeon.
5. The program must be at an institution affiliated with a histocompatibility laboratory member.
6. The program must be at an institution affiliated with an organ procurement organization member.
7. The program must perform at least 20 pancreas transplants each year to qualify for pancreas transplantation training.
8. The training program must have adequate clinical and laboratory research facilities.
9. The training program should have adequate faculty with appropriate training to provide proper research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new training program.

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.5.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 its foreign equivalent. In the case of a surgeon who has just completed training and whose board certification in thoracic surgery is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 24-month period.

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

- The formal cardiothoracic surgery residency pathway, as described in *Section H.2.A. Cardiothoracic Surgery Residency Pathway* below.
- The 12-month heart transplant fellowship pathway, as described in *Section H.2.B. Twelve-month Heart Transplant Fellowship Pathway* below.
- The heart transplant program clinical experience pathway, as described in *Section H.2.C. Clinical Experience Pathway* below.

A. Cardiothoracic Surgery Residency Pathway

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

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the cardiothoracic surgery residency. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon during the cardiothoracic surgery residency. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, recipient

selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.

4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
 - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

B. Twelve-month Heart Transplant Fellowship Pathway

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

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon during the 12-month heart transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical circulatory assist devices,

recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.

4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
 - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

C. Clinical Experience Pathway

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

1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program or its foreign equivalent. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant

patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.

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

D. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary heart transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's heart transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections H.2.A through H.2.C* above.
2. The surgeon has maintained a current working knowledge of all aspects of heart transplantation and patient care, defined as direct involvement in heart transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

H.3 Primary Heart Transplant Physician Requirements

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

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

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

- The 12-month transplant cardiology fellowship pathway, as described in *Section H.3.A. Twelve-month Transplant Cardiology Fellowship Pathway* below.
- The clinical experience pathway, as described in *Section H.3.B. Clinical Experience Pathway* below.

A. Twelve-month Transplant Cardiology Fellowship Pathway

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

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients.

This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.

2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology or American Board of Pediatrics certified fellowship training program in pediatric cardiology or its foreign equivalent, as accepted by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
 - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the Primary Physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program or its foreign equivalent. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

C. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's heart transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections H.3.A and H.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN Obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

D. Conditional Approval for Primary Transplant Physician

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

1. The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months experience on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
4. The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
5. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another heart transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:

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

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

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

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

Appendix I: Membership and Personnel Requirements for Lung Transplant Programs

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.5.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 its foreign equivalent. In the case of a surgeon who has just completed training and whose board certification in thoracic surgery is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 24-month period.

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

- The formal cardiothoracic surgery residency pathway, as described in *Section I.2.A. Cardiothoracic Surgery Residency Pathway* below.
- The 12-month lung transplant fellowship pathway, as described in *Section I.2.B. Twelve-month Lung Transplant Fellowship Pathway* below.
- The lung transplant program clinical experience pathway, as described in *Section I.2.C. Clinical Experience Pathway* below.

A. Cardiothoracic Surgery Residency Pathway

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

1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or heart/lung transplants as primary surgeon or first assistant under the direct supervision of a qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung transplant program. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and

postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must also include the other clinical requirements for thoracic surgery

4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
 - b. A letter of recommendation from the program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

B. Twelve-month Lung Transplant Fellowship Pathway

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

1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the program.
2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon during the 12-month lung transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
 - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

C. Clinical Experience Pathway

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

1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated lung transplant program, or its foreign equivalent. At least half of these transplants must be lung procedures, and at least 10 must be performed as the primary surgeon. The surgeon must also have been actively involved with cardiothoracic surgery. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from program where the experience was gained.

2. The surgeon has performed at least 10 lung procurements. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the program where the surgeon gained experience verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
 - b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

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.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

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 their foreign equivalent.

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

- The 12-month transplant pulmonary fellowship pathway, as described in *Section I.3.A. Twelve-month Transplant Pulmonary Fellowship Pathway* below.
- The clinical experience pathway, as described in *Section I.3.B. Clinical Experience Pathway* below.

A. Twelve-month Transplant Pulmonary Fellowship Pathway

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

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
 - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation

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

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

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 15 or more newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period on an active lung transplant program or its foreign equivalent. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and

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

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

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.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

D. Conditional Approval for Primary Transplant Physician

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

1. The physician is a pulmonologist with current board certification in pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months of experience on an active lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has been involved in the primary care of 8 or more newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be lung transplant recipients. This care must be documented in a recipient log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
4. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
5. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The program has established and documented a consulting relationship with counterparts at another lung transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC

to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary lung transplant physician by the end of the 12 month conditional approval period.

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

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

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

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

Appendix J:

Membership and Personnel Requirements for Joint Heart and Lung Programs

A designated heart and lung transplant program must have current approval as a designated heart transplant program *and* a designated lung transplant program as described in:

- *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*

Designated heart and lung 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.

J.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician

A heart and 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 in *Sections J.2 and J.3*. 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.5.B. Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

J.2 Primary Heart and Lung Transplant Surgeon Requirements

A designated heart and lung transplant program must have on site a qualified transplant surgeon who meets the requirements for primary heart transplant surgeon *or* primary lung transplant surgeon as defined in these Bylaws.

J.3 Primary Heart and Lung Transplant Physician

A designated heart and lung transplant program must have on site a qualified transplant physician who meets the requirements for primary heart transplant physician *or* primary lung transplant physician as defined in these Bylaws.

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.

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.
- 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.9 Review of Transplant Program Functional Activity* 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 UNetSM 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.5.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, resulting in an inactive UNetSM waiting list status and an inactive membership status.

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.

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. 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, Actions, and Due Process* 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. 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.
4. 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.
 5. 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.
 6. 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 Status 1A and 1B 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 UNetSM. 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.

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, Actions, and Due Process

L.1. Member Compliance

Each OPTN member agrees to comply with OPTN Obligations, which include *all* of the following:

1. National Organ Transplant Act, as amended, *42 U.S.C. 273 et seq.*
2. OPTN Final Rule, *42 CFR Part 121*
3. OPTN Bylaws
4. OPTN Policies

At any time, the OPTN Board of Directors or the OPTN Executive Committee may recommend that the Secretary of the U.S. Department of Health and Human Services (HHS) take appropriate action as outlined in the OPTN Final Rule.

A. Periodic Reviews

The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital, histocompatibility laboratory member, and OPO member for compliance with OPTN Obligations. All compliance monitoring is performed using guidelines developed by the OPTN. Any member who fails to fulfill all the applicable OPTN Obligations may be subject to actions as set forth in these Bylaws.

B. Failure to Pay OPTN Fees

The failure of an OPO, transplant hospital, or histocompatibility laboratory member to pay, within 30 days, any OPTN fee, charge, or other monetary obligation to the OPTN Contractor will be considered a violation of OPTN Obligations.

L.2. Compliance Monitoring

The OPTN Executive Director monitors compliance of members with OPTN Obligations, and refers all incidences of potential non-compliance for further review as outlined in these Bylaws.

The Executive Director may delegate these monitoring duties to any number of designees to ensure that the necessary actions are taken to meet the requirements of these Bylaws.

L.3. Reporting Potential Violations and Non-compliance

Any member who becomes aware of a potential violation of or non-compliance with OPTN Obligations must inform the OPTN as soon as the member becomes aware of the

issue, including potential violations or non-compliance by the member itself.

L.4. Methods for Correspondence and Providing Notice

Unless otherwise noted, all correspondence between members and the OPTN required by this *Appendix L* must be sent 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

The Executive Director will send notice to members when they are required to respond to an OPTN action or request. When the member receives notice, the member must respond within the specified time, as defined in these Bylaws. Time limits specified for providing notice, including requests for interviews, hearings, and to appear before the OPTN Board of Directors, begin on the date the notice is sent from the Executive Director.

L.5. Medical Peer Review

The OPTN will conduct all deliberations and take all actions according to applicable confidential medical peer review laws. As appropriate and consistent with applicable laws, all of the following deliberations and actions of any OPTN Committee, the OPTN Executive Committee, the OPTN Board of Directors, and the OPTN Contractor will be kept confidential during the review of:

1. Potential violations of or non-compliance with OPTN Obligations.
2. Matters relating to potential threats to patient health and public safety.
3. Applications for membership, designated transplant program status, or a change in Key Personnel.

Members must keep these records, review activity, and documents confidential to promote quality improvement and full disclosure by OPTN members.

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, 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.

L.6. Requests for Root Cause Analysis and Corrective Action

The OPTN Board of Directors, the MPSC, or any standing subcommittee of the MPSC or their designee may require a member to take corrective action to address any potential violation or noncompliance. Corrective action can include any of the following:

1. Root cause analysis
2. Corrective action plan
3. Plan for quality improvement
4. On-site monitoring
5. Desk monitoring
6. Self-assessments
7. External expert consultants

A. Initiating Corrective Action

If it appears that an OPO, transplant hospital, or histocompatibility laboratory member may have failed to meet OPTN Obligations, the MPSC or the Board of Directors may request that the member performs a root cause analysis and then develops and implements a corrective action plan or plan for quality improvement to address any potential violations or non-compliance.

B. Fulfilling Requests for Root Cause Analysis and Corrective Action

The Executive Director will promptly give notice to the member when requesting any corrective action. The member must also submit any requested documentation to the Executive Director at this time.

L.7. Special Secretarial Reviews

The Secretary of HHS may request that the OPTN Contractor performs a Special Review under guidance from the Secretary. 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, and as defined *Sections L.6 and L.9 through L. 14* in this *Appendix L*. Members must fully comply with all OPTN Contractor requests as part of a Special Review.

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.

L.8. Review Pathways for Potential Violations

The OPTN will review potential violations of and non-compliance with OPTN Obligations by one of three pathways as defined below:

1. An **Imminent Threat Review** will be conducted when the MPSC Chair determines that there is a potential violation of or non-compliance with OPTN Obligations, which may pose an urgent and severe risk to patient health or public safety. The MPSC Chair may choose this pathway when the member is not taking action to mitigate the potential threat, or the Chair believes that the potential threat may not be mitigated through routine procedures.
2. An **Expedited Review** will be conducted when the MPSC Chair determines that a potential violation of or non-compliance with OPTN Obligations may pose a potential risk to patient health or public safety, which is not currently urgent but could become urgent or severe if not addressed using an Expedited Review process. When a matter is reviewed using the Expedited Review pathway, a hearing is offered to the member on an expedited schedule.
3. A **Routine Review** will be conducted for any potential violation of or non-compliance with OPTN Obligations when the MPSC Chair determines that an Expedited Review or an Imminent Threat Review is not warranted.

When investigating any potential violation or non-compliance and determining a review pathway, the OPTN Contractor will take appropriate action as described in *Sections L.9 through L. 14* that follow.

L.9. Preliminary Investigation of Potential Violations

When the OPTN learns of a possible failure of a member to comply with any aspect of applicable OPTN Obligations, the Executive Director will conduct a preliminary investigation. This investigation will consider whether the potential violation suggests a risk to patient health or public safety, and the urgency and severity of the risk.

If additional information is required in conducting the preliminary investigation of any potential violation, the member must respond to requests from the OPTN. A member's documented history of violations and non-compliance, or systemic problems and operational failures, could warrant review of the member through the Imminent Threat or Expedited Review pathway.

A. Referral of Potential Violations to the MPSC Chair

If the preliminary investigation concludes that the potential violation may pose an urgent and severe risk to patient health or public safety, the matter will be referred to the MPSC Chair within 24 hours.

If the preliminary investigation concludes that the risk to patient health or public safety is not an urgent and severe risk, but a substantial risk remains, the matter will be referred to the MPSC Chair within 7 days.

B. Notice to the Secretary after Preliminary Investigation

If the potential violation is referred to the MPSC Chair with a recommendation to follow the Imminent Threat Review pathway, the Executive Director will provide notice to the Secretary within 24 hours of the referral.

The OPTN will notify the Secretary within 7 days when a preliminary investigation determines that the member has not violated OPTN Obligations but that a risk to patient health or public safety exists.

L.10. Determination of Review Pathway

A. MPSC Chair’s Determination of Urgency and Severity

The OPTN will refer a potential violation to the MPSC Chair if the preliminary investigation determines that the potential violation may pose an urgent and severe risk to patient health or public safety. The MPSC Chair will consider the available information and determine the appropriate review pathway. In making this determination, the MPSC Chair may consult with the Executive Director, OPTN President, HRSA representatives, and any others, as determined by the Chair. If the MPSC Chair is unavailable, the MPSC Vice Chair may make this determination.

The MPSC Chair must make this decision within 72 hours after the preliminary investigation is completed.

B. Requests to Take Action to Mitigate Imminent Threat

If the MPSC Chair determines that an urgent and severe risk appears to be present, the MPSC Chair may request that the member voluntarily cease performing certain transplants or take a specified action to mitigate the threat to patient health or public safety. If the member takes the requested action to mitigate the threat within 24 hours, the matter may proceed through the Expedited Review pathway.

C. Notice of Chair’s Determination

The MPSC Chair will provide notice to the Secretary of the Review pathway within 72 hours of the determination.

D. Changing Review Pathways

The MPSC Chair may change the review pathway of a potential violation at any time as information is gathered and the assessment of the urgency and severity of the risk to patient health or public safety changes.

L.11. OPTN Investigations

After the preliminary investigation of a potential violation or incident of non-compliance and the review pathway has been determined, additional investigation will occur as required. The investigation of any potential violation or non-compliance conducted by the OPTN may include, but is not limited to, *any* of the following:

1. Data review
2. Document review
3. Interviews with the member’s representatives
4. On-site visits by OPTN Contractor staff
5. On-site visits by peer review teams

L.12. Imminent Threat Reviews

When the MPSC Chair determines that a potential violation of or non-compliance with OPTN Obligations presents an urgent and severe risk to patient health or public safety, and the member has not voluntarily taken the requested action to mitigate the risk, the potential violation will proceed through the Imminent Threat Review pathway. The OPTN Executive Director will notify the member immediately when the MPSC Chair determines that a potential violation will proceed through the Imminent Threat Review pathway.

A. Imminent Threat Review Investigation

The OPTN must complete an investigation of the potential violation within 14 days of the initial determination by the MPSC Chair that the potential violation will proceed through the Imminent Threat Review pathway.

B. Imminent Threat Review Committee

Within 21 days of the determination of the imminent threat review pathway, the Imminent Threat Review Committee will complete its review of the matter and forward its recommendations to the MPSC Chair.

1. Composition of the Imminent Threat Review Committee

The Imminent Threat Review Committee may be the MPSC, any standing subcommittee of the MPSC, or an ad hoc subcommittee of the MPSC, as

appointed by the MPSC Chair. A subcommittee must include at least 5 members of the MPSC, and 2 of the members must have expertise in the organ system or specific issue that is the subject of the review.

2. Imminent Threat Review Committee Recommendation

The Imminent Threat Review Committee will determine whether the matter should continue to follow the Imminent Threat Review process.

If the Imminent Threat Review Committee determines that an urgent and severe risk to patient health or public safety no longer exists, it will determine whether the matter should proceed through the Expedited Review or Routine Review pathway.

3. Notice after Imminent Threat Review Committee Recommendation

When the Imminent Threat Review Committee determines that a potential violation will continue through the Imminent Threat Review pathway, the OPTN Executive Director will:

- a) Provide notice to the member of the Imminent Threat Review Committee's action within 24 hours by an approved method as described in *Section L.4.Methods for Correspondence and Providing Notice*. The member will have 24 hours after receiving notice to respond to the Executive Director regarding the Imminent Threat Review Committee's recommendations.
- b) Provide notice of the Imminent Threat Review Committee's recommendation to the Secretary within 24 hours.
- c) Refer the matter to the OPTN Executive Committee within 72 hours.
- d) Include a recommendation for an adverse action, and whether the matter should be referred to the Secretary for further action.

C. Interviews in Imminent Threat Reviews

When a potential violation proceeds through the Imminent Threat Review pathway, members are *not* entitled to an interview before the MPSC, even though the recommended action is an adverse action.

D. OPTN Executive Committee Determination

The Executive Committee of the OPTN will convene within 7 days of the Imminent Threat Review Committee's determination.

If the Executive Committee determines that an urgent and severe risk to patient health or public safety no longer exists, it will decide whether the matter should proceed through the Expedited Review or Routine Review pathway.

If the matter continues to proceed through the Imminent Threat Review pathway, the Executive Committee will make the following determinations:

1. Whether to accept the recommendation of the Imminent Threat Review Committee, or take another action. An adverse action is effective immediately upon the determination by the Executive Committee, prior to any hearing.
2. Whether the MPSC, Executive Committee, or Board of Directors will be the hearing body if the member requests a hearing. Members of the Imminent Threat Review Committee may also participate in the Imminent Threat Hearing Panel.

E. Notice after OPTN Executive Committee’s Determination

The OPTN Executive Director will provide notice of the Executive Committee’s determinations:

1. To the HHS Secretary within 24 hours.
2. To the member within 24 hours.

The Executive Committee will provide a written summary of this review to the Executive Director within 48 hours to be forwarded to the Secretary. The Executive Committee may determine when any notice to the membership or public required by Executive Committee actions will occur. The member may request a copy of the supporting documentation, which will be provided at the member’s expense.

F. Requesting a Hearing in Imminent Threat Reviews

The member has 7 days following notice of the Executive Committee’s determination to request a hearing as described in *Section L.18.B*.

Requesting a Hearing. The hearing will occur not less than 7 days or more than 30 days from the date of the Executive Director’s receipt of the request for a hearing.

G. Imminent Threat Hearing Process

If the member exercises its right to a hearing, the hearing will be conducted under the procedures described in *Section L.18.Hearings* that follows, with these modifications:

1. The hearing will occur after the Executive Committee’s review and determination of the adverse action.
2. The Hearing Panel report will be issued within 14 days of the conclusion of the hearing.
3. If the Imminent Threat Hearing Panel determines that no adverse action is warranted, the Hearing Panel may immediately remove the designation of Member Not in Good Standing or Probation and provide appropriate notice without Board of Directors’ approval.

L.13. Expedited Reviews

Any potential violation of or non-compliance with OPTN Obligations that poses a potential risk to patient health or public safety, which could become urgent or severe, will follow the Expedited Review pathway.

A. Expedited Review Investigation

The OPTN must complete an investigation of the potential violation within 21 days of the initial determination by the MPSC Chair that the potential violation will proceed through the Expedited Review pathway.

B. Expedited Review Committee

Within 42 days of the determination of the expedited review pathway, the Expedited Review Committee will complete its review and forward its recommendations to the MPSC Chair.

1. Composition of the Expedited Review Committee

The Expedited Review Committee may be the MPSC, any standing subcommittee of the MPSC, or an ad hoc subcommittee of the MPSC, as appointed by the MPSC Chair. A subcommittee must include at least 5 members of the MPSC and 2 of the members should have expertise in the organ system or specific issue that is the subject of the review.

2. Expedited Review Committee Recommendations

The Expedited Review Committee will consider instances of potential non-compliance with OPTN Obligations. The Expedited Review Committee may determine that there was no violation, issue a letter of warning, or issue a notice of uncontested violation. The Expedited Review Committee may also recommend a Letter of Reprimand or an adverse action.

If the Expedited Review Committee recommends a Letter of Reprimand or an adverse action, then the member is entitled to an interview before the MPSC.

3. Notice after Expedited Review Committee's Recommendations

The MPSC Chair will provide notice of the Expedited Review Committee's determination by an approved method as described in *Section L.4.Methods for Correspondence and Providing Notice*. If the recommendation is for an adverse action, then the OPTN Executive Director will provide notice of the Expedited Review Committee's determination to the Secretary within 24 hours.

C. Interviews in Expedited Reviews

The member will be entitled to an interview before the MPSC when the Expedited Review Committee considers issuing a Letter of Reprimand or an adverse action. The member will have the right to request an interview to be held at the next in-person meeting of the MPSC. If the next in-person meeting of the MPSC is scheduled more than 60 days later, at the discretion of the MPSC Chair, a special in-person meeting may be required or an interview may be conducted by teleconference or electronic media.

If the member exercises its right to an interview, the interview will be conducted as described in *Section L.17. Interviews* that follows.

1. Requesting an Interview

The member has 14 days following notice of the Expedited Review Committee’s recommendation to request an interview before the MPSC as described in *Section L.17.B.Requesting an Interview*.

D. Requesting a Hearing in Expedited Reviews

Following the interview before the MPSC, whether accepted by the member or not, the MPSC will consider the Expedited Review Committee’s recommendation and may recommend to the Board of Directors to impose an adverse action on the member. The MPSC will provide Notice of the recommended adverse action to the member. The member has 14 days following notice of the MPSC’s recommendation for an adverse action to request a hearing as described in *Section L.18.B. Requesting a Hearing*.

Hearings will be scheduled no fewer than 7 days or more than 60 days from the date that the Executive Director receives the request for hearing. Hearings may be scheduled more than 60 days from the request date at the discretion of the MPSC Chair, and if the member and Chair agree on the date.

E. Expedited Review Hearing Panel

The Expedited Review Hearing Panel will be appointed by the MPSC Chair and composed of at least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc committee. Two of the members must have expertise in the organ system or specific issue that is the subject of the review.

The Chair of the MPSC or the Chair’s designee will be the presiding officer. Members of the Expedited Review Committee may also participate in the Expedited Review Hearing Panel.

F. Expedited Review Hearing Process

If the member exercises its right to a hearing, the hearing will be conducted under the procedures described in *Section L. 18.Hearings* that follows, with these modifications:

1. The Hearing Panel report will be issued within 21 days of the conclusion of the hearing.
2. The Board will consider and act on the Hearing Panel report within 30 days of receiving the report.

L.14. Routine Reviews

A Routine Review will be conducted for any potential violation of OPTN Obligations when an Expedited Review or an Imminent Threat Review is not warranted.

A. Routine Review Investigations

The OPTN will complete a routine review investigation of the matter and refer it to the Routine Review Committee within 6 months.

B. Routine Review Committee

The Routine Review Committee will be composed of any standing subcommittee of the MPSC or, at the discretion of the MPSC Chair, the entire MPSC. The Routine Review Committee may meet by teleconference or electronic media, as needed, for the purpose of considering any new and ongoing potential policy violations.

1. Notice after Routine Review Committee's Determinations

The Routine Review Committee will notify the member of its determination and any recommendation for a specific action. If the Committee recommends an action that would entitle the member to an interview, members will be notified of their right to an interview at the time they are informed of the Committee's determination.

C. Interviews in Routine Reviews

The member will be entitled to an interview when the Routine Review Committee is considering making a recommendation for a Letter of Reprimand or an adverse action. Interviews will be scheduled at the next in-person meeting of the MPSC or standing subcommittee of the MPSC.

1. Requesting an Interview

The member has 14 days to request an interview as described in *Section L. 17.B.Requesting an Interview* following notice of the Routine Review Committee's determination. If the member waives its rights to an

interview, the MPSC may proceed to issue its recommendation for an adverse action or Letter of Reprimand.

D. Hearings in Routine Reviews

1. Requesting a Hearing

The member has 14 days following notice of the Routine Review Committee's recommendation for an adverse action to request a hearing as described in *Section L.18.B. Requesting a Hearing*.

Hearings will be scheduled no fewer than 7 days or more than 60 days from the date the OPTN Executive Director receives the request for hearing. Hearings may be scheduled more than 60 days from the request date at the discretion of the MPSC Chair, and if the member and MPSC Chair agree on the date.

2. Routine Review Hearing Panel

The Routine Review Hearing Panel will be appointed by the MPSC Chair and composed of at least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc committee. Two of the members must have expertise in the organ system or specific issue that is the subject of the review.

The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of the Routine Review Committee may also participate in the Routine Review Hearing Panel.

3. Routine Review Hearing Process

If the member exercises its right to a hearing, the hearing will be conducted using the procedures described in *Section L.18.Hearings*, with the following additional notifications to the member:

- a) That all documentation about the member that was generated by or submitted to the MPSC, the OPTN Executive Committee, or the OPTN Board before the recommendation or action, will be made available to the member, upon request.
- b) The Hearing Panel report will be issued within 30 days of the conclusion of the hearing.
- c) The Board of Directors will consider and act on the Hearing Panel report at its next regularly scheduled meeting following receipt of the report.

L.15. OPTN Determinations and Actions

OPTN actions may be imposed when a member:

1. Fails to comply with OPTN Obligations as described in *L.1. Member Compliance*.
2. Fails to submit or follow a corrective action plan or plan for quality improvement.
3. Fails to meet personnel requirements.
4. Acts in a way that poses a risk to patient health or public safety.
5. Fails to act as necessary to avoid risk to patient health or public safety.

A. Determining Appropriate Action

Factors considered in reviewing potential violations and incidents of non-compliance include but are not limited to:

1. Whether the potential violation poses an urgent and severe risk to patient health or public safety.
2. Whether the potential violation poses a substantial risk to the integrity of or trust in the OPTN.
3. Whether patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the potential violation occurred.
4. Whether the member can show evidence of corrective action upon learning of the potential violation.
5. The overall OPTN compliance history of the member, including but not limited to, MPSC reviews and actions in the member's history.

The OPTN may impose a separate action for each violation or may choose to impose a single action for all related violations that can be addressed by a single action.

B. Corrective Action

The OPTN may require a member to take corrective action in addition to imposing an adverse action, or instead of imposing an adverse action, including:

1. Root cause analysis
2. Corrective action plan
3. Plan for quality improvement
4. On-site monitoring
5. Desk monitoring
6. Self-assessments
7. External expert consultants

If the MPSC or any standing subcommittee of the MPSC requires a member to take corrective action to address any issues of noncompliance, the member must take corrective action as specified and within the period provided. If the member

fails to fulfill the corrective action requirements, the OPTN may make any determination or take any action as outlined in this *Appendix L*.

C. Deferred Disposition with Monitoring Period

If the MPSC recommends an adverse action against a member, and the member has had an interview before the MPSC, the MPSC may delay proceeding with the matter for a Deferred Disposition period. Deferred Disposition will only be considered in cases where the member has implemented a corrective action plan or plan for quality improvement within the 60 days prior to the interview and where the potential violation or non-compliance under review is not egregious or severe.

Deferred Disposition is not an action, but rather a timeout period provided to the member to demonstrate its ability and willingness to meet OPTN Obligations. If the MPSC chooses to employ a Deferred Disposition, the recommendation for adverse action will not be communicated to the Board of Directors until after Deferred Disposition. The MPSC is able to revise its recommendation at the end of the Deferred Disposition before communicating it to the Board.

Deferred Disposition is not appropriate if the member has received *either*:

1. A Letter of Warning, Letter of Reprimand, or an MPSC recommendation for an adverse action in the previous 2 years from the date of the interview.
2. Two or more Notices of Uncontested Violation in the previous 2 years from the date of the interview.

1. Additional Considerations for Deferred Disposition

The MPSC may also consider any of the following:

- a) The overall performance and compliance history of the member, including its response to previous MPSC actions, and particularly requests for corrective action or plans for quality improvement.
- b) Any recent changes in the member's staffing, including changes in those responsible for oversight of the member.
- c) An MPSC assessment of the appropriateness or thoroughness of the corrective action plan or plan for quality improvement addressing the matter under review.

The MPSC is not required to offer a Deferred Disposition after an interview with the member and may proceed with its recommendation of the adverse action without a Deferred Disposition. If the member declines the Deferred Disposition, the MPSC will proceed with its recommendation of the adverse action.

2. Notice of Deferred Disposition

Notice of an MPSC determination of Deferred Disposition is not an adverse action recommendation that entitles the member to a hearing.

Deferred Disposition will include a 6-month monitoring period, beginning on the date of the interview. During this period, the member will have to demonstrate compliance with OPTN Obligations as outlined in its corrective action plan or plan for quality improvement. An on-site review of the member will be completed during the monitoring period.

3. Monitoring during Deferred Disposition

The member’s compliance will be monitored by a subcommittee of the MPSC. The subcommittee will provide updates of that monitoring to the MPSC at any regular meetings of the MPSC scheduled during the Deferred Disposition.

4. Recommendation of an Adverse Action during or after Deferred Disposition

If the member does not demonstrate to the MPSC’s satisfaction that the member has achieved compliance during the Deferred Disposition, the MPSC will proceed with its recommendation of an adverse action. The MPSC may proceed with its recommendation of the adverse action at any point during Deferred Disposition. If the MPSC proceeds with its recommendation of an adverse action, the member will be notified of its right to a hearing.

5. Actions if Member Demonstrates Compliance after Deferred Disposition

The MPSC may consider imposing a non-adverse action or taking no action if the MPSC believes that the member has demonstrated compliance with OPTN Obligations or sufficient quality improvement at the end of the Deferred Disposition.

D. MPSC Actions without Board Referral

The MPSC, or any standing subcommittee of the MPSC, may take any of the following actions or recommendations directly:

- Issue a Notice of Uncontested Violation
- Issue a Letter of Warning
- Consider Issuing a Letter of Reprimand

These actions and recommendations do not require Board of Directors approval. The Board of Directors and the Secretary of HHS will be notified any time a Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand is issued, or anytime Deferred Disposition is offered.

1. Notice of Uncontested Violation

The MPSC, or any standing subcommittee of the MPSC, will issue a Notice of Uncontested Violation for a violation of OPTN Obligations when:

- a) There is substantial evidence of mitigating factors based on medical judgment.
- b) There is believed to be no likelihood of recurrence.
- c) The member does not challenge that the violation occurred.

The member is not entitled to an interview.

2. Letter of Warning

The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Warning for a violation of OPTN Obligations when:

- a) Medical judgment is credibly put forth as a partial mitigating factor.
- b) There is believed to be no likelihood of recurrence.

Letters of Warning may also be issued in those cases where the compliance history of the member warrants an action higher than Notice of Uncontested Violation. The member is not entitled to an interview.

3. Letter of Reprimand

The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Reprimand for a violation of OPTN Obligations when medical judgment does not appear to be a credible mitigating factor. Letters of Reprimand may also be issued in those cases where the compliance history of the member warrants an action higher than Notice of Uncontested Violation or Letter of Warning. The member is entitled to an interview before a Letter of Reprimand is issued.

E. Adverse Actions that Require Board Approval

The adverse actions of Probation and Member Not in Good Standing can only be imposed by the Board of Directors. If a member receives an adverse action, the Executive Director will give notice to the public of the adverse action as specified by the Board of Directors. This notice may include, but is not limited to, communication using the OPTN website.

1. Probation

The MPSC may recommend that the Board of Directors place a member on Probation, or the Board may do so on its own. Probation is an adverse action under these Bylaws, and the OPTN Executive Director will give notice to all members when a member is placed on Probation.

a) **Corrective Action Requirements**

The adverse action of Probation will require that the member adheres to corrective action requirements as specified by the MPSC, which may include, but are not limited to:

- i. Required development and submission of a corrective action plan or plan for quality improvement as specified by the MPSC, any standing subcommittee of the MPSC, the Executive Committee, or the Board of Directors. The member must demonstrate that it has adhered to the plan and that it has corrected any noncompliant activity within the Probation effective period.
- ii. Unscheduled on-site reviews by the OPTN Contractor staff or peer review teams throughout the Probation period.
- iii. Specified submission of reports, data, or other evidence to the OPTN that documents correction of the non-compliant activity throughout the period of Probation.

2. Member Not in Good Standing

The MPSC may recommend that the Board of Directors declare the member to be a Member Not in Good Standing, or the Board of Directors may do so on its own. Member Not in Good Standing is an adverse action under these Bylaws.

The adverse action of Member Not in Good Standing will include:

- a) Notice to the Secretary of HHS.
- b) Loss of member voting privileges in OPTN affairs.
- c) Loss of the privilege of any personnel associated with the member to serve on any Committee or the Board of Directors, or to hold office.
- d) Formal notification, along with any subsequent changes in status, to the entire OPTN membership.
- e) Formal notification, along with any subsequent changes in status, to the member's Chief Executive Officer or Administrator.
- f) Formal notification, along with any subsequent changes in status, to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the member's state.
- g) Any actions that can be taken under Probation.

3. Notification Requirements of Probation and Member Not in Good Standing

A member receiving the adverse action of Member Not in Good Standing must provide notice of the adverse action as follows:

If the member is a...	Then notice must be provided to ...
Transplant hospital	All transplant hospital patients as defined in these Bylaws.
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.

Members must provide notices as described above within 30 days of receiving notification from the OPTN that it has been given the adverse action.

The member must send the notice to each new transplant hospital patient as defined in these Bylaws during the entire effective period of the adverse action. The notice to transplant hospital patients must be provided in writing, in each patient’s spoken language, and as specified by the Executive Committee or Board of Directors.

The Board may impose additional requirements regarding the form and timing of the notification.

F. 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.16* that follows.

At any time, the Board may make recommendations to the Secretary for specific actions, on its own or after receiving a recommendation from the MPSC.

L.16. Secretarial Actions

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.16.A: 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 removed 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:

- a) 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.
- b) Termination of the member's reimbursement under Medicare or Medicaid.
- c) Termination of a transplant hospital's participation in Medicare or Medicaid.
- d) Request for information from the OPTN.
- e) Any other action that the Secretary considers necessary.

A. 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.

B. Effective Date of Actions Recommended by the Board

Actions recommended by the OPTN Board of Directors and taken by the Secretary for non-compliance 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.

If the Board 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 may recommend that a Secretarial action be made effective immediately, before completing any required interview or hearing.

L.17. Interviews

An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural rules followed for hearings. The member will be informed of the reasons for the interview and may present any information it considers useful and relevant.

A. Members' Right to an Interview

The member will have the right to an interview when:

1. A Letter of Reprimand is recommended.
2. An adverse action is recommended.
3. A membership application or application for designated transplant program status is rejected.

However, a member has no right to an interview when a potential violation is being reviewed through the Imminent Threat Review pathway. After the interview is completed, the MPSC will promptly provide a summary of the interview to the member.

B. Requesting an Interview

A member who fails to request an interview within the specified time waives any right to an interview. The member must submit its written interview request to the Executive Director using one of the approved methods described in *L.4.Methods for Correspondence and Providing Notice*.

The failure to request an interview means that:

If the recommended action is a non-adverse action, the action will be issued. If the recommended action is an adverse action, the member is entitled to a hearing.

C. Notice of Interview

When the Executive Director receives a request for an interview from the member within the time and in the manner required, the interview will be

conducted at the next in-person meeting of the MPSC.

D. Notice to Member after an Interview

The MPSC Chair will promptly provide notice to the member of the MPSC’s recommendations or actions resulting from the interview. The notice will:

1. Briefly advise the member of the nature of the action.
2. Advise the member of the right to a hearing, if applicable, according to the provisions of these Bylaws.
3. Specify the maximum number of days that the member has to submit a request for a hearing.

E. Informal Discussion

The MPSC, or any subcommittee of the MPSC, may request that the member participate in an informal discussion to provide additional details regarding a potential violation of or non-compliance with OPTN Obligations or to gain additional information regarding member performance. The discussion is informal, and may be conducted by teleconference or electronic media. This informal discussion is intended to provide the member the opportunity to provide clarification of the matter, and could lead to a more timely and effective assessment and resolution of the matter.

L.18. Hearings

If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse action without recommendation from the MPSC, the member is entitled to a hearing.

A. Members’ Right to a Hearing

The member has a right to a hearing when an adverse action is:

1. Recommended by the MPSC.
2. Recommended by a subcommittee of the MPSC, if the action is the rejection of an initial membership application or application for designated transplant program status.
3. A result of a determination regarding a potential violation undergoing an Imminent Threat Review.
4. Taken by the Board of Directors or the Executive Committee notwithstanding a favorable recommendation by the MPSC or standing subcommittee of the MPSC under circumstances where no right to a hearing existed.
5. Taken by the Board of Directors or the Executive Committee on its own without a prior recommendation by the MPSC.

If the Board of Directors determines, based on available evidence that a potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the Board may take action even if the member has not had the opportunity for a hearing.

B. Requesting a Hearing

The member must submit its written hearing request to the OPTN using one of the approved methods described in *Section L.4.Methods for Correspondence and Providing Notice*. A member who fails to request a hearing within the specified time waives any right to a hearing.

If the member will be represented by an attorney at the hearing, the request for a hearing must identify by name the attorney who will represent the member, and include the attorney's business address and contact information.

The failure to request a hearing means that the member accepts the adverse action or recommendation and the following outcomes will apply:

1. An adverse recommendation by the MPSC or the Executive Committee will become effective after the final decision of the Board of Directors.
2. An adverse action by the Board of Directors will become effective and considered the final decision by the Board.

C. Notice of Hearing

When the Executive Director receives a request for a hearing within the period and in the required manner, the Executive Director will send notification of the time, place, and date of the hearing to the member at least 7 days before the hearing.

The hearing notice will include a concise statement of the adverse recommendation or action that is the subject of the hearing, and be delivered to the member using an approved method as described in *Section L.4.Methods for Correspondence and Providing Notice*.

At this time, all documentation about the member that was available to the MPSC, the Executive Committee, or the Board at the time of deliberation, will be provided to the member, upon request and at the member's expense.

D. Appointment of Hearing Panels

Hearing Panels will be appointed according to the review pathway of the potential violation as described in:

- *Section L.12.Imminent Threat Reviews*

- *Section L.13. Expedited Reviews*
- *Section L.14. Routine Reviews*

Alternatively, at the discretion of the President, those Board members who are in attendance at a regular or special meeting of the Board may conduct the hearing, provided that the members comprise a quorum of the full Board. One of the members will be designated as Chair of the Hearing Panel.

E. Hearing Participants

Hearing participants will be:

1. The Hearing Panel.
2. The member being reviewed for the adverse recommendation or action.

F. Service on Hearing Panels

Hearing Panel members must avoid conflicts of interest according to *Article 2.7 Conflicts of Interest* of these Bylaws, and will be disqualified from serving on a Hearing Panel if the member has been directly involved in compiling evidence or providing expert consultation to the OPTN on the matter being reviewed.

G. Appearance and Representation at Hearings

The member who requested the hearing must appear in person at the hearing. A member who fails without good cause to appear at a requested hearing will waive its rights to a hearing. The member, the body whose recommendation resulted in the hearing, and the Hearing Panel may be represented by an attorney.

H. Presiding Officer

The Chair of the MPSC or the Chair's designee will be the presiding officer. The presiding officer will manage the hearing to ensure that all participants in the hearing have the opportunity to present relevant evidence and to conduct any necessary cross-examination required for a full disclosure of the facts.

The presiding officer will determine the order of procedure during the hearing and make all rulings on interpretation or construction of the OPTN Obligations, relevant documents, OPTN requirements on procedure, and on the admissibility of evidence. The presiding officer makes all decisions regarding the exclusion of irrelevant, immaterial, redundant, or repetitive evidence.

I. Rights of Hearing Participants

During a hearing, the member and the Hearing Panel will have the right, subject

to the presiding officer's rulings, to:

1. Call and examine witnesses.
2. Introduce exhibits.
3. Cross-examine any witness on any matter relevant to the issue.
4. Impeach any witness.
5. Refute any evidence.

The Hearing Panel may call and question any member representatives who are present at the hearing, even if they do not testify as witnesses for the member or the member chooses not to testify on its own behalf.

J. Procedure and Evidence

The hearing need not be conducted strictly according to rules of law relating to the examination of witnesses or presentation of evidence. The presiding officer may permit admission of any relevant information, regardless of whether such evidence would be admitted in a court of law.

Each party will, before or during the hearing, be entitled to submit documents concerning any relevant issue, and these documents will become part of the hearing record. The presiding officer may, but is not required to, order that oral evidence is taken only on oath or affirmation. The oath or affirmation may be administered by any person designated by the presiding officer and who is authorized to notarize documents in the state where the hearing is held.

K. Official Notice

In reaching a decision, the Hearing Panel may take official notice at any time during the hearing of any generally accepted technical, scientific, or medical information relating to the issues under consideration.

When the Hearing Panel takes official notice of any information, participants will be informed of the information considered and that information will be noted in the hearing record. Any participant may request that information be given official notice. Hearing participants may challenge any information given official notice, either by providing evidence or expert witness testimony.

L. Burden of Proof

The body whose adverse recommendation or action resulted in the hearing must present evidence to support the adverse recommendation or action, including an explanation of the action or recommendation, and the reason it was taken. The member will then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks

substantial basis or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious.

M. Hearing Record

The Hearing Panel will keep a record of the hearing that includes a hearing transcript and any documents reviewed during the hearing. A court reporter will prepare the written transcript. All exhibits admitted into evidence at the hearing and all documents submitted to the Hearing Panel will be incorporated in the record until the hearing is declared adjourned.

N. Postponement

Request for postponement of a hearing will be granted by the MPSC Chair only for good cause and only if the request is made as soon as is reasonably possible.

O. Presence of Hearing Panel

The Hearing Panel must be present throughout the hearing and deliberations. If a Panel member is absent from any part of the proceedings, the Panel member will not be permitted to participate in the Panel's deliberations or the decision.

P. Recesses and Adjournment

The Chair of the Hearing Panel may recess the hearing and reconvene within 60 days or when reasonably practical for the convenience of the participants, to obtain material new or additional information, or to consult with experts.

When the presentation of oral and written evidence is concluded, the hearing will be closed. The Hearing Panel will then, at a time convenient to the Panel, conduct its deliberations away from the parties. When the Hearing Panel completes its deliberations, the hearing will be declared finally adjourned.

Q. Action after Hearing

At the conclusion of their deliberations, the Hearing Panel will do *one* of the following:

1. Issue a recommendation for an adverse action.
2. Issue a lesser action.
3. Recommend that the MPSC close the review of the potential violation without issuing any action.

A hearing cannot remain open or be re-opened after the hearing panel has taken an action.

R. Hearing Panel Report

Following preparation of the hearing record, the Hearing Panel will make a written report of its findings and recommendations and will forward it, together with the hearing record, to the Board of Directors. At the same time, a copy of the Hearing Panel report will be forwarded to the member. The Hearing Panel report will be approved by the presiding officer before it is provided to the Board of Directors and member.

All findings and recommendations by the Hearing Panel will be supported by references to the hearing record. The presiding officer may extend the time for making the Hearing Panel's written report at his or her discretion by giving written notice to the participants.

S. Notice after Hearing

The Executive Director will promptly send a copy of the result of the Hearing to the member by an approved method as described in *Section L.4.Methods for Correspondence and Providing Notice*. A copy of the result also will be provided to the Board of Directors.

T. Effect of Favorable Result

If the Hearing Panel closes the matter without recommending an adverse action, then no further due process is required.

U. Effect of Adverse Result

If the result of the hearing continues to be adverse to the member, the adverse recommendation will be forwarded to the Board of Directors to make a final decision. The member will have the right to request to appear before the Board of Directors before a final action is taken by the Board.

L.19. Final Decision of the Board of Directors

A. Right to Appear before the Board

Before the Board of Directors takes final action regarding any recommendation for adverse action, the member has the right to appear before the Board and submit a written statement and provide oral statement that details any disagreement with the findings of fact, conclusions, or procedural issues raised at any step in the review process.

The member requesting to appear before the Board must submit a written request to the OPTN Executive Director using one of the approved methods as described in *Section L.4.Methods for Correspondence and Providing Notice*. Members must provide to the Executive Director any written statements that will

be submitted to the Board at least 15 days before the scheduled appearance.

At least 25 days before the member is scheduled to appear before the Board, the Executive Director will provide notice to the member of the time, place, and date.

B. Board of Directors Action

After the conclusion of appropriate due process proceedings and after the MPSC forwards a recommendation to the Board of Directors, the Board will make its final decision in the matter. At this time, the Board will send written notice of its decision to the member and to the Secretary of HHS within 3 business days of the final decision. Written notice will be sent by an approved method as described in *Section L.4.Methods for Correspondence and Providing Notice*.

The Board may take longer than 3 days to provide notice of its decision for good reason, as determined by the Secretary. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws.

1. Terms of Probation

A Board action placing a member on Probation will be effective only after hearing proceedings have been concluded, or the member has waived its right to a hearing, and final Board action is taken.

Probation may also be made effective at any time the Board finds, based on available information, that the potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety.

2. Terms of Member Not in Good Standing

When the Board takes the adverse action of Member Not in Good Standing, the action will be effective only after hearing proceedings have been concluded, or the member has waived its right to a hearing, and final Board action is taken.

Member Not in Good Standing may also be made effective at any time the Board finds, based on available information, that the potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety.

3. Board Recommendations to the Secretary

A Board of Directors' recommendation that the Secretary take action against a member will not become effective until after applicable hearing proceedings have been concluded or the member has waived its right to a hearing, unless the Board finds, at any time, based on available information, that the potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety.

The action that the Board recommends the Secretary take will not become effective until the Secretary of HHS accepts the Board's recommendation, or takes other action that the Secretary determines is appropriate.

C. Notice

Notice of a final decision by the Board of Directors that the member has been placed on Probation or declared a Member Not in Good Standing will be circulated to all members as described in *Section L.15. OPTN Determinations and Actions*. OPTN membership will be notified of final decisions by the Board to recommend to the Secretary of HHS Suspension or Termination of membership only after the Secretary approves the recommendation.

L.20. Restoration of Unrestricted Membership Privileges

If a member that is given Probation or declared a Member Not in Good Standing 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 Board of Directors restore unrestricted membership privileges.

If Secretarial Action has been taken against a member as described in *Section L.16. Secretarial Actions*, only the Secretary of HHS can restore its unrestricted membership privileges. The MPSC may recommend that the Secretary of HHS restore unrestricted membership privileges if Secretarial Action has been taken against a member if 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.

If a membership was suspended or terminated by the Secretary, the member must complete and submit an application for OPTN membership, as described in *Appendix A: Membership Application and Review*.

A. Request for Restoration of Membership Privileges

A member may request restoration of membership privileges after it demonstrates to the satisfaction of the MPSC that:

1. The member is in compliance with OPTN Obligations.
2. The member has fully implemented any corrective action plan or a plan for quality improvement previously required by the MPSC.
3. The member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.
4. The type of violation that resulted in the adverse action is not likely to recur.

5. There are no pending compliance issues that may lead to a potential violation or non-compliance that would require an Imminent Threat Review.

The burden is on the member at all times to demonstrate that restoration of membership privileges is appropriate.

B. Minimum Requirements to Request Restoration of Membership Privileges

The MPSC will only consider requests for restoration of membership privileges during its regularly scheduled meetings and the member may not request restoration of membership privileges until *both* occur:

At least twelve months have passed since the approval and implementation of the MPSC prescribed corrective action plan.

At least twelve months have passed since the approval of the final action by the Board of Directors or the Secretary of HHS.

If the MPSC denies the member’s request for restoration of membership privileges, the member may renew its request 6 months from the date the MPSC denied the request.

C. Additional Requirements

At its discretion, the MPSC may require any of the following before it considers a request for restoration of privileges:

1. An unannounced OPTN Contractor on-site review.
2. An unannounced peer on-site review.
3. Data and document review.
4. A presentation to the MPSC by the member.

D. Hearing

If the MPSC denies the member’s request for restoration of privileges and the member has met the conditions identified above, then the member will be entitled to a hearing at the next regularly scheduled MPSC meeting. The member must submit a written hearing request using one of the approved methods described in *Section L.4.Methods for Correspondence and Providing Notice*. The hearing will be held at the member’s expense, as outlined in *Section L.23.Costs and Expenses*.

E. Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule

If the member presents evidence to the MPSC’s satisfaction that a member

found to be in violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule has fully complied with OPTN Obligations, including completing any corrective actions prescribed, the MPSC will recommend to the Board of Directors that full membership privileges be restored.

L.21. Lesser Adverse Actions

The MPSC may consider a lesser adverse action if a member requests either restoration of unrestricted membership or a lesser adverse action. The MPSC may recommend to the Board of Directors the lesser adverse actions of Probation or, if the existing action is Probation, a trial restoration period.

The MPSC may consider the recommendation if the member has demonstrated to the MPSC's satisfaction all of the following:

1. The member is now in compliance with OPTN Obligations.
2. The underlying cause for the adverse action is corrected.
3. The corrective action plan or plan for quality improvement has been implemented.
4. The type of violation that resulted in the adverse action is not likely to recur.
5. There are no pending compliance issues that may lead to a potential violation or non-compliance that would require an Imminent Threat Review.

The burden is on the member at all times to demonstrate that a lesser adverse action is appropriate.

A. Requesting a Lesser Adverse Action

The burden is on the member at all times to demonstrate that a lesser adverse action is appropriate. However, the MPSC will only consider requests during its regularly scheduled meetings.

The member may not request a lesser adverse action until *both* occur:

At least twelve months have passed since the approval and implementation of the MPSC prescribed corrective action plan.

At least twelve months have passed since the approval of the final action by the Board of Directors or the Secretary of HHS.

In its discretion, the MPSC may require an unannounced on-site review or peer on-site review before considering the request.

B. Considering Requests for Lesser Adverse Actions

The consideration of lesser adverse actions does not entitle the member to an interview or hearing under these Bylaws. If the MPSC denies the request by the member and the member believes that the MPSC acted arbitrarily and

capriciously, the member will be entitled to a hearing regarding the recommendation for the action of Probation or trial reinstatement period at the next regularly scheduled meeting of the MPSC. The hearing will be held at the member's expense.

If the MPSC denies the member's request for a lesser adverse action, the member may renew its request 6 months after the MPSC denies the request.

L.22. Rejected Membership Applications

If an application for membership, designated transplant program status, or a Change in Key Personnel is rejected the applicant has the same due process rights given to a member as outlined in this *Appendix L*.

An applicant for membership or designated transplant program status has the right to appeal to the Secretary of HHS decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications according to Section 121.10(c) of the OPTN Final Rule.

If an applicant exercises this right of appeal before exhausting the procedural rights granted in these Bylaws, the applicant will provide written notice to the Executive Director by an approved method as described in *Section L.4.Methods for Correspondence and Providing Notice*. When the Executive Director receives notice, it will notify the Secretary of the appeal within 3 business days, or a longer period if necessary, as determined by the Secretary. Pending a decision on the appeal, due process procedures will continue unless the Secretary directs otherwise.

If the appeal to the Secretary is denied, the rejection process may continue, according to *Appendix A: Membership Application and Review* of these Bylaws. Any other decision by the Secretary on the appeal will be submitted to the MPSC or Board for action consistent with the Secretary's decision.

L.23. 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:

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 presiding officer, after consultation with the Executive Director, 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.10. A. Transplant Program Survival Rates* 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, and intestines. 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

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.

Functional Inactivity

Functional inactivity is when a transplant program meets *any or all* of the following:

1. The inability to serve potential candidates, candidates, recipients, or living donors for a period of 15 or more consecutive days.
2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.
3. The failure to perform a transplant during the periods defined in the table below:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

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 serves at least one transplant hospital within its service area. 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

An organ procurement organization that is not independent from the transplant hospital it serves. All OPOs must be designated by the Centers for Medicare and Medicaid Services (CMS) and are responsible for the procurement of organs for transplantation and the promotion of organ donation. Hospital-based OPOs are held to the same standards and requirements as OPO 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 *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. An OPO member must be an IOPO to have a vote on OPTN business. 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.

Informal Discussion

An informal discussion is not an adverse action or an element of due process. An informal discussion is conducted according to the principles of confidential medical peer review, as described in *Appendix L* of these Bylaws. An informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. An informal discussion may be held with a member regarding performance reviews, or when a transplant program is seeking approval for a transplant surgeon through the predominantly pediatric pathway.

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.

L

Long-term Inactivity

A transplant program that is inactive for 15 or more consecutive days. Long-term inactivity results in an inactive UNetsm waiting list status and an inactive membership status.

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.

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.

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

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). 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 Organization (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.

Regional Review Boards (RRBs)

Peer review panels established in each of the 11 regions to review all urgent status listings for liver and heart candidates. The RRB reviews justification forms submitted by each center documenting the severity of the candidate's illness and justifies the status at which the candidate is listed. Liver RRBs review listings for all liver candidates in Status 1, special case exceptions for MELD/PELD liver candidates, and hepatocellular carcinoma (HCC) candidates. Thoracic RRBs review listings for heart candidates in Status 1A and special case heart candidates in Status 1B. These boards also consider appeals of cases initially refused for a particular medical urgency status.

Regions

For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the membership is divided into 11 geographic regions. Members belong to the region in which they are located.

The regions are as follows:

- Region 1** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
- Region 2** Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
- Region 3** Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
- Region 4** Oklahoma, Texas
- Region 5** Arizona, California, Nevada, New Mexico, Utah
- Region 6** Alaska, Hawaii, Idaho, Montana, Oregon, Washington
- Region 7** Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
- Region 8** Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
- Region 9** New York, Western Vermont
- Region 10** Indiana, Michigan, Ohio
- Region 11** 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*.

UNetSM

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. UNetSM 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

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), 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. The criteria include, for example, organ type, geographic local and regional area, genetic compatibility measures, details about the condition of the organ, the candidate's disease severity, and time spent waiting.

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.