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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Brian M. Shepard
UNOS Director of Policy

RE: Summary of actions taken at the OPTN/UNOS Board of Directors Meeting
— June 21-22, 2010

Date: July 22, 2010

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its June 2010 meeting.

This format allows you to scan the Board's actions and quickly determine what is required of you. The notice also includes the specific changes to OPTN/UNOS bylaws and policies. If you are interested in reviewing policy changes from previous board meetings, go to www.unos.org, click on "Newsroom," and then select "View all Policy Notices."

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

Overview of Policy Modifications/Board Actions and Affected Professionals

Who should be aware of these actions? Please review the 7 notices included on the grid below and share with other colleagues as appropriate.

	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Compliance Officers	Page #
1	Modification of Policy 3.4 (Organ Procurement, Distribution, and Alternative Systems for Distribution or Allocation) to Improve the Variance Appeals Process (<i>Policy Oversight Committee</i>)	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	3
2	Adding a Valuable Consideration Disclosure to the Bylaws (<i>Living Donor Committee</i>)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	4
3	Change in OPTN Patient Registration Fee and UNOS Computer Registration Fee (<i>Finance Committee</i>)	X	X		X	X		X	X	X				X				5
4	Policy 3.5.11.2 (Quality of Antigen Mismatch) Update (<i>Kidney Transplantation Committee</i>)	X	X	X	X	X	X	X		X			X	X			X	6
5	Clarification to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) (<i>Liver and Intestinal Organ Transplantation Committee</i>)								X	X	X	X		X		X		7
6	Modification to Reverse an Earlier Motion that Status 1A/1B Cases Not Meeting Criteria Must Be Retrospectively Reviewed by the Regional Review Boards (<i>Liver and Intestinal Organ Transplantation Committee</i>)									X	X	X	X		X		X	8
7	Modifications to Permit Flexibility in the Method for Transmitting Required Communications (<i>Membership and Professional Standards Committee</i>)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	9

Title of Policy Change: Modification of Policy 3.4 (Organ Procurement, Distribution, and Alternative Systems for Distribution or Allocation) to Improve the Variance Appeals Process

Sponsoring Committee: Policy Oversight Committee (POC)

Policy Affected: Policy 3.4 (Organ Procurement, Distribution, and Alternative Systems for Distribution or Allocation)

Effective Date: August 22, 2010

Professional Groups Affected by the Change: OPO Executive Directors, Directors of Organ Procurement, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, and Transplant Physicians.

Problem Statement	Changes	What You Need to Do
Policy 3.4 describes the process for OPOs and transplant programs to apply for, review, and modify the various alternative systems. The current policy language does not address the steps OPTN members must take to appeal a decision by the reviewing committees or the Board of Directors. Current policy also does not clearly define the roles of the reviewing committees.	The modifications describe how an OPTN member may appeal a variance decision. The modifications also describe the role of the relevant committees and POC in the appeal process.	OPOs and transplant centers should be aware that the policy has been modified. If your variance application is denied, you will be notified by the committee that reviewed your variance within 10 business days. These 10 days include the meeting in which the committee determined the outcome of the alternative organ distribution or allocation system. This notification will provide information about the appeals process, including the requirement that you have 30 days from the time you are notified of a decision to alert the OPTN of your intent to appeal.

Title of Bylaw Change: Adding a Valuable Consideration Disclosure to the Bylaws

Sponsoring Committee: Living Donor Committee

Bylaw Affected: Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplantation

Effective Date: August 22, 2010

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
In July 2009, federal authorities charged an individual with allegedly violating the federal law that prohibits the sale or purchase of human organs. After being notified of this case, the Living Donor Committee considered additional actions that could be taken to limit or prevent the illegal sale and purchase of living donor organs in the future.	The Board of Directors modified consent requirements in the bylaws to require that transplant centers disclose to potential living donors that the sale or purchase of human organs is a federal crime.	Transplant program staff must document that they have informed potential living donors that the sale or purchase human organs is a federal crime. This documentation must be an element of your program's informed consent protocol. Transplant programs must provide this documentation to the OPTN contractor upon request.

Title of Board Action: Change in OPTN Patient Registration Fee and UNOS Computer Registration Fee

Sponsoring Committee: Finance Committee

Policy Affected: Policy 11.0 (Registration Fee)

Effective Date: October 1, 2010

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Lab Directors

Problem Statement	Changes	What You Need to Do
Further funding is required for OPTN and UNOS operations in FY 2011 (October 1, 2010 – September 30, 2011) for regular operating expenses and core computer programming to manage the OPTN.	The OPTN Board of Directors approved an increase in the OPTN patient registration fee from \$557 to \$585, subject to final approval by HRSA. Separately, the UNOS Board of Directors approved an increase in the UNOS computer registration fee from \$114 to \$119. A \$30 component of this fee provides funding to upgrade computer systems.	Notify program finance departments of impending change.

Title of Policy Change: Policy 3.5.11.2 (Quality of Antigen Mismatch) Update

Sponsoring Committee: Kidney Transplantation Committee

Policy Affected: Policy 3.5.11.2 (Quality of Antigen Mismatch)

Effective Date: July 22, 2010

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Coordinators, Transplant Program Directors, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
Currently, Policy 3.5.11.2 (Quality of Antigen Mismatch) directs readers to a document that is no longer produced and maintained by the OPTN Contractor.	The Board of Directors updated policy language to reflect that the antigen equivalency tables cited in policy are now located in Policy Appendix 3A.	Please refer to Appendix A for Policy 3 when in need of the antigen equivalency tables.

Title of Policy Change: Clarification to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC))

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

Policy Affected: Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC))

Effective Date: July 22, 2010

Professional Groups Affected by the Change: Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Data Coordinators

Problem Statement	Changes	What You Need to Do
<p>Policy 3.6.4.4 describes the criteria for Stage 2 HCC tumors in two sections- the first paragraph of the policy, and within Table 3, the American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Staging Classification. Currently, these descriptions are not identical regarding the maximum size of a single tumor:</p> <ul style="list-style-type: none">• The text in the first paragraph of Policy 3.6.4.4 permits a single tumor “less than 5cm.”• Table 3 defines a single noduleT2 tumor as “2.0 - 5.0 cm,” allowing a single tumor as large as 5cm in diameter.	<p>The Board of Directors modified the text in the first paragraph of Policy 3.6.4.4 to be consistent with the Milan criteria outlined in Table 3 and with UNetSM programming.</p>	<p>Transplant centers should be aware that the policy has been modified.</p>

Title of Policy Change: Modification to Reverse an Earlier Motion that Status 1A/1B Cases Not Meeting Criteria Must Be Retrospectively Reviewed by the Regional Review Boards

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

Policy Affected: Policies 3.6.4.1 (Adult Candidate Status) and 3.6.4.2 (Pediatric Candidate Status)

Effective Date: August 22, 2010

Professional Groups Affected by the Change: Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Data Coordinators

Problem Statement	Changes	What You Need to Do
<p>The Liver Committee’s Status 1A/1B Review Subcommittee reviews Status 1A/1B cases that don’t meet the criteria outlined in policy. This subcommittee makes recommendations to the committee regarding the appropriateness of the listings.</p> <p>In December 2006, the Board approved a committee recommendation to send these cases to the Regional Review Boards for retrospective review. In April 2010, the Committee determined that these reviews should remain with the subcommittee, and unanimously recommended restoring the previous language.</p>	<p>Status 1A and 1B cases that don’t meet the criteria in policy will still be reviewed by a subcommittee of the Liver Committee.</p>	<p>Transplant centers should be aware of the process for review of these cases.</p>

Title of Bylaw Change: Modifications to Permit Flexibility in the Method for Transmitting Required Communications

Sponsoring Committee: Membership and Professional Standards Committee

Bylaws Affected: OPTN Bylaws Article I, 1.11 (Removal of Non-Qualifying Members) and 1.12 (Meetings); Article II, 2.6 (Meetings); Article X, 10.2 (Notice); Appendix A, 2.04A (Requests), 2.11 (Procedural Rights), 3.01A (Definition of "Adverse"), 3.02A (Hearings), 3.03A (Appellate Review), 4.01A (Board of Directors Action), 6.03A (Default in Payment of Reimbursable Cost and Expenses); Appendix B, II. C. (Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status)

UNOS Bylaws Article I, 1.11 (Removal of Non-Qualifying Members) and 1.12 (Meetings); Article II, 2.6 (Meetings); Article X, 10.2 (Notice); Appendix A, 2.04A (Requests), 2.11 (Procedural Rights), 3.01A (Definition of "Adverse"), 3.02A (Hearings), 3.03A (Appellate Review), 4.01A (Board of Directors Action), 6.03A (Default in Payment of Reimbursable Cost and Expenses)

Effective Date: August 22, 2010

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff, Compliance Officers

Problem Statement	Changes	What You Need to Do
Currently, the bylaws limit delivery of many communications to specific services that are provided by the United States Postal Service (USPS). The stringency of the current bylaws effectively prohibits other delivery methods that meet security and tracking needs, and are also faster and often less costly than USPS services.	The Board of Directors modified the bylaws to permit the use of any delivery method that can be tracked and/or provides a proof of receipt rather than limiting delivery to certified mail or certified mail/return receipt requested. In addition, the new bylaw language allows for the use of future innovations in delivery methods without another revision to the bylaws.	Transplant professionals should be aware of the bylaw modifications and become familiar with alternate methods of delivery such as secure electronic communication.

Affected Policy Language:

- 3.4 ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION.** The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

[There are no changes to Policies 3.4.1 through 3.4.7 where indicated]

- 3.4.8 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the processes for applying for a new or modified AAD System, review of such systems and withdrawal from such systems by any one or more of the participants.

3.4.8.1 Application. *(No changes)*

3.4.8.2 Data Submission Requirements. *(No changes)*

3.4.8.3 Dissolution of Alternative Assignment Systems. *(No changes)*

3.4.8.4 Modifications of Alternative Point Assignment Systems, Sharing Arrangements and ALUs. *(No changes)*

3.4.8.5 AAD Systems Approved Prior to March 15, 2005. *(No changes)*

3.4.8.6 Appealing A Decision on An Alternative Organ Distribution or Allocation System. A participating Member can appeal a committee's or a Board of Directors' decision on an alternative organ distribution or allocation system. To appeal a decision on an alternative organ distribution or allocation system, the participating Member must follow the process described below.

a. Appealing A Committee's Decision

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the alternative organ distribution or allocation system.

To express its intent to appeal a committee's decision on an alternative organ distribution or allocation system, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would the application (see Policy 3.4.7.1 – Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the alternative organ distribution or allocation system, the participating Member *cannot request another appeal* until the POC *and* the Board of Directors decide on the alternative organ distribution or allocation system.

In its evaluation of the alternative organ distribution or allocation system, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the alternative organ distribution or allocation system and submit its recommendation to the Board of Directors. The Board of Directors will consider the alternative organ distribution or allocation system, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is approved for the trial period requested by the participating Member. If the Board of Directors decides against the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is not approved.

b. Appealing a Board of Directors' Decision

To appeal the decision of the Board of Directors on an alternative organ distribution or allocation system, the participating Member of the alternative organ distribution or allocation system may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

3.4.9 Application, Review, Dissolution and Modification Processes for Variances.

The following policies define the processes for applying for a new or modified Variance, review of such systems by, and withdrawal from such systems by any one or more participants.

3.4.9.1 Application. *(No changes)*

3.4.9.2 Data Requirements. *(No changes)*

3.4.9.3 Appeal to Secretary. ~~Decisions of the Board of Directors to approve a Variance may be appealed to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR § 121.4.~~

3.4.9.3 Appealing A Variance Decision. The participating Member can appeal a committee's or Board of Directors' decision on a variance. To appeal a decision on a variance, the participating Member must follow the process described below.

a. Appealing a Committee's Decision

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.

To express its intent to appeal, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would a variance application (see Policy 3.4.8.1 – Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the variance, the participating Member *cannot request another appeal* until the POC *and* the Board of Directors decide on the variance.

In its evaluation of the variance, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the variance and submit its recommendation to the Board of Directors. The Board of Directors will consider the variance, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the variance, then the variance is approved for the trial period requested by the

participant. If the Board of Directors decides against the variance, then the variance is not approved.

b. Appealing a Board of Directors' Decision

To appeal the decision of the Board of Directors, the variance applicant may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

3.4.9.4 Termination of Member Participation in Variance. *(No changes)*

3.4.9.5 Modification of Variance. *(No changes)*

3.4.10 Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems. The following policies define the processes for developing a new or modified Committee-Sponsored Alternative System, application to participate in such systems, review of such systems, and withdrawal from such systems by any one or more participants.

3.4.10.1 Development and Application. *(No changes)*

3.4.10.2 Data Requirements. *(No changes)*

3.4.10.3 Termination of Member Participation in Committee-Sponsored Alternative System. *(no changes)*

3.4.10.4 Modification of Committee-Sponsored Alternative System. *(no changes)*

3.4.10.5 Committee-Sponsored Alternative Systems Approved Prior to March 15, 2005. *(no changes)*

3.4.10.6 Appealing A Decision on A Committee-Sponsored Alternative System.

The committee sponsoring a Committee-Sponsored Alternative System may appeal the decision of the Policy Oversight Committee (POC), but cannot appeal a decision of the Board of Directors.

a. Appealing the POC's Decision

The POC will notify the sponsoring committee in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.

To express its intent to appeal, the sponsoring committee must do so in writing and within 30 days, inclusive, of the POC's communication of its decision. The sponsoring committee must

appeal the POC's decision *before* the Board of Directors reviews the POC's recommendation.

In considering the appeal, the POC will *only review evidence not considered previously*. The POC will evaluate the appeal as it would an application for a Committee-Sponsored Alternative System (see Policy 3.4.9.1 – Development and Application). The sponsoring committee may choose to take part in this appeal discussion. The POC may request additional information from the sponsoring committee. Once the POC makes its final decision on the variance, the sponsoring committee *cannot request another appeal* until the Board of Directors decide on the Committee-Sponsored Alternative System.

In its evaluation of the Committee-Sponsored Alternative System, the POC may request additional information from the sponsoring committee. Once the sponsoring committee submits any information requested by the POC, the POC will then decide on the Committee-Sponsored Alternative System and submit its recommendation to the Board of Directors. The Board of Directors will consider the Committee-Sponsored Alternative System. The sponsoring committee may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is approved for the trial period requested by the committee. If the Board of Directors decides against the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is not approved.

b. Appealing the Board of Directors' Decision

Only a member participating in an existing Committee-Sponsored Alternative System can appeal the Board of Directors' decision on a Committee-Sponsored Alternative System.

To appeal the decision of the Board of Directors on a Committee-Sponsored Alternative System, the member participating in an approved Committee-Sponsored Alternative System may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

[There are no further changes to Policy 3.4.]

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Bylaw Language:**Proposed Modification to Bylaws, Appendix B, Attachment I, Section XIII, C (2), Designated Transplant Program Criteria.****XIII. Transplant Programs.****(1) Kidney Transplant [No Changes]****(2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants****a-b (iii) (4) [No Changes]**

(iv) Informed Consent. Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
- (5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor;
- (6) the telephone number that is available for living donors to report concerns to the OPTN
- (7) documentation of disclosure by the transplant center to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

Proposed Modification to Bylaws, Appendix B, Attachment I, Section XIII, C (4), Designated Transplant Program Criteria.

XIII. Transplant Programs.

(3) Liver Transplantation [No Changes]

(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.

a-b (iii) (4) [No Changes]

(iv) Informed Consent. Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
- (5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor;
- (6) the telephone number that is available for living donors to report concerns or grievances to the OPTN
- (7) documentation of disclosure by the transplant center to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:**11.0 REGISTRATION FEE**

The Registration Fee, as provided in Article I, Section 1.13 of the Bylaws for the listing of candidates as required by Policy 3.2.1 for listing a potential recipient in UNetSM, shall consist of two separate fees. These fees shall be the OPTN Patient Registration Fee ~~\$557~~ \$585 and the UNOS Computer Registration Fee ~~\$114~~ \$119.

NOTE: The amendments to UNOS Policy 11.0 (Registration Fee) shall be effective October 1, 2010.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

Affected Policy Language:

3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a candidate based on the number of mismatches between the candidate's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:

- 2 points if there are no DR mismatches, as defined in the table below or;
- 1point if there is 1 DR mismatch as defined in the table below.

HLA Mismatch Definitions*

Mismatch Category	# HLA Locus		
	A	B	DR
0 ABDR MM	0	0	0
0 DR MM	0	1	0
	0	2	0
	1	0	0
	1	1	0
	1	2	0
	2	0	0
	2	1	0
	2	2	0
1 DR MM	0	0	1
	0	1	1
	0	2	1
	1	0	1
	1	1	1
	1	2	1
	2	0	1
	2	1	1
	2	2	1

- Antigens that are considered to be equivalent for matching purposes are currently shown in ~~Appendix C of UNetSM User's Manual~~. Appendix A to Policy 3.
[...]

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC). Candidates with Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the Waiting List as specified below. A candidate with an HCC tumor that is greater than or equal to 2 cm and less than or equal to 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months. The largest dimension of each tumor must be reported (i.e., 3.2cm x 5.1cm must be reported as 5.1cm).

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

3.6.4.1 Adult Candidate Status. Medical urgency is assigned to an adult liver transplant candidate (greater than or equal to 18 years of age) based on either the criteria defined below for Status 1A, or the candidate’s mortality risk score as determined by the prognostic factors specified in Table 1 and calculated in accordance with the MELD Scoring System. A candidate who does not have a MELD score that, in the judgment of the candidate’s transplant physician, appropriately reflects the candidate's medical urgency, may nevertheless be assigned a higher MELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the higher MELD score. The justification must include a rationale for incorporating the exceptional case as part of MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the MELD criteria.

Status Definition

7 A candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.

1A A candidate greater than or equal to 18 years of age listed as Status 1A has fulminant liver failure with a life expectancy without a liver transplant of less than 7 days. For the purpose of Policy 3.6, fulminant liver failure shall be defined as described in (i)-(iv). Centers that list candidates not meeting these criteria for Status 1A will ~~have the case retrospectively reviewed by the Regional Review Board (RRB). Cases not resolved at the regional level will~~ be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(iv) will be listed in Status 1A without RRB review.

<< No further changes to Policy 3.6.4.1 >>

3.6.4.2 Pediatric Candidate Status. Medical urgency is assigned to a pediatric liver transplant candidate (less than 18 years of age) based on either the criteria defined below for Status 1A or 1B, or the candidate’s mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance with the Pediatric End-Stage Liver Disease Scoring System (PELD) for pediatric candidates <12 years or with the MELD System (defined above in Policy 3.6.4.1) for pediatric candidates 12-17 years. Based on the variables included in allocation score calculation in the MELD system, MELD scores may offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Pediatric candidates 12-17 years will use a risk score calculated with the MELD system while maintaining other priorities assigned to pediatric candidates. A candidate who does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgement of the candidate’s transplant physician, appropriately reflects the candidate’s medical urgency or was listed at less than 18 years of age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to a higher or the appropriate PELD or MELD score and pediatric classification (for candidates listed at less than age 18 who turn age 18) upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgement, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the PELD or MELD criteria.

Status Definition

7 A pediatric candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.

1A/1B A pediatric candidate listed as Status 1A or 1B is located in the hospital's Intensive Care Unit (ICU). For purposes of Status 1A/1B definition and classification, candidates listed at less than 18 years of age who remain on or have returned to the Waiting List upon or after reaching age 18 may be considered Status 1A/1B and shall qualify for other pediatric classifications under the following criteria. There are five allowable diagnostic groups: (i) fulminant liver failure; (ii) primary non function; (iii) hepatic artery thrombosis; (iv) acute decompensated Wilson’s Disease; and (v) chronic liver disease. Candidates meeting criteria (i) (ii), (iii), or (iv) may be listed as a Status 1A; those meeting criteria (v) may be listed as a Status 1B. Within each diagnostic group specific conditions must be met to allow for listing a pediatric candidate at Status 1A

or 1B. Centers that list candidates not meeting these criteria for Status 1A or 1B will ~~have the case retrospectively reviewed by the Regional Review Board (RRB). Cases not resolved at the regional level will~~ be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(v) will be listed in Status 1A or Status 1B without RRB review.

<< No further changes to Policy 3.6.4.2 >>

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Bylaw Language:**OPTN BYLAWS, ARTICLE I, MEMBERS****1.11 Removal of Non-Qualifying Members.**

- a. Transplant center Institutional Members that fail to qualify as an OPTN Member under Article 1.2(b) shall be treated in accordance with Article II of Appendix B to these Bylaws.
- b. All other OPTN Members who cease to qualify for OPTN membership under Article I of these Bylaws may be removed as OPTN Members in accordance with the following procedures:
 1. The Member may request removal from OPTN membership by forwarding a written request therefor to the OPTN, or
 2. Even if the Member does not request removal, the OPTN may notify the Member in writing that, unless the Member demonstrates that it continues to meet applicable membership criteria within sixty (60) days of notification, the Member's OPTN membership will be terminated.
 - i. If, within sixty (60) days of such notification, the Member demonstrates, to the satisfaction of the OPTN, that the Member continues to meet OPTN membership requirements, the OPTN shall withdraw its notice of termination.
 - ii. If the Member fails to demonstrate that it continues to meet applicable OPTN membership requirements, its membership in the OPTN will terminate on the sixtieth (60th) day after notification of termination by the OPTN. The Member can appeal this decision to the Secretary of HHS. In the event a Member exercises this right of appeal, the Member shall notify the OPTN Contractor of this exercise by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary shall be submitted to the Membership and Professional Standards Committee or Board of Directors as appropriate for action consistent with the Secretary's decision.
- c. Any Member that requests removal from OPTN membership or is otherwise removed from OPTN membership under this Article 1.11 may later re-apply for membership in accordance with Article 1.7 of these Bylaws.

- 1.12 Meetings.** The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Member Electors, Public Organization Member Electors, Medical/Scientific Member Electors, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to the OPTN. Meetings of the OPTN membership typically shall be open to the public; however, discussions involving confidential matters including, OPTN member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract. Representatives from the Federal

government serving on the Board of Directors, or their designees, shall not be precluded from attending such closed sessions of OPTN meetings.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be ~~mailed~~ provided to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

Article II Board of Directors

- 2.6 Notice of Meetings.** Written notice of any regular or special meeting of the Board of Directors shall state the place, date, and time of the meeting and shall be ~~mailed~~ provided to each Director at the address on file with the Executive Director not fewer than 10 or more than 60 days before the date of the meeting. The Executive Director shall circulate the agenda for each Board of Directors meeting to the Members at least 10 days prior to the meeting in order to promote input from the Members to the Directors. A written waiver of notice signed by a Director, whether before or after the time stated therein, shall be the equivalent of the giving of any notice required herein. A Director who attends a meeting shall be deemed to have had timely and proper notice thereof.

Article X Amendment of Charter and Bylaws

- 10.2 Notice.** Notice of any meeting at which an amendment to the Charter or Bylaws is proposed shall be ~~sent by mail~~ provided to each Director at the address on file with the Executive Director no fewer than 10 or more than 60 days before the date of the meeting, accompanied by a copy of the proposed amendment.

APPENDIX A TO BYLAWS - OPTN
Application and Hearing Procedures for Members and Designated Transplant Programs
Corrective Action and Enforcement of OPTN Requirements
OPO, Transplant Hospital, and Histocompatibility Laboratory Members

2.04A - Requests

All requests for corrective action to enforce OPTN requirements shall be submitted to the MPSC in writing by the Executive Director or his/her designee, and shall be supported by reference to the specific activities or conduct which constitute the grounds for the request. The Executive Director, or his/her designee, shall promptly give notice of such request for corrective action to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested.~~

2.11A - Procedural Rights

Procedural rights, including "interviews and hearings," are further described in Section 3.01A – 3.03A of the Bylaws. If the Member does not deliver a written request for an interview to the chairperson of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~ within 14 days following his receipt of such notice, the Member waives its rights to an interview and the MPSC may proceed to implement its proposed action.

Interviews and Hearings

3.01A - Definition of "Adverse"

- (1) **Recommendations or Actions:** Subject to Section 3.01a (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01a (2) below, entitle the applicant or Member affected thereby to a hearing:
 - (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of Member Not in Good Standing and subsequent determinations not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension.
 - (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), including, by way of example and not limitation, removal of designation as a transplant program.
- (2) **When Deemed Adverse:** A recommendation or action listed in section 3.01a (1) above shall be deemed adverse only when it has been:
 - (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or

- (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.
- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSCPCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

- (4) **Right to a Hearing:**
- (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.
 - (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:
 - (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily

inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to OPTN requirements), the MPSC subcommittee shall further recommend approval from the Secretary to suspend member privileges, terminate membership or designated transplant program status, and/or take action specified in the OPTN Final Rule.

- (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director.
- (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~ (as well as facsimile transmission), and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense.
- (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of decisions by the Executive Committee or Board to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendation by the Secretary.
- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

- (5) **Right of Appeal to the Secretary.** An applicant for membership or designation as a transplant program shall have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. In the event an applicant exercises this right of appeal prior to exhaustion of the applicant's other procedural rights as described in these Bylaws, the applicant shall notify the OPTN Contractor of this exercise by a method that can be tracked and that

provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. Upon receiving such notification, the OPTN Contractor shall notify the Secretary of the status of the matter with respect to these procedures within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary shall be submitted to the MPSC or Board of Directors as appropriate for action consistent with the Secretary's decision.

3.02A – Hearings

- (1) **Parties:** The parties to a hearing shall be the applicant or Member against whom an adverse recommendation or action has been taken and the MPSC, the Executive Committee, or the Board of Directors, i.e., the body whose adverse recommendation or action is at issue.
- (2) **Notice of Adverse Recommendation or Action:** An applicant or Member against whom an adverse recommendation or action has been taken shall promptly be given notice of such action by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. Such notice shall:
 - (a) Briefly advise the applicant or Member of the nature of the adverse recommendation or action and the grounds therefor; and
 - (b) Advise the applicant or Member of the right to a hearing pursuant to the provisions of these Bylaws; and
 - (c) Specify the number of days following the date of receipt of notice within which a request for a hearing must be submitted; and
 - (d) State that the failure to request a hearing within the specified time period shall constitute a waiver of rights to a hearing and to any appellate review of the matter; and
 - (e) State that all materials about the applicant or Member that were generated by or submitted to the MPSC, the Executive Committee, or the Board, as the case may be, prior to that body's adverse recommendation or action, shall be made available to the applicant or Member, upon request, for inspection and copying; and
 - (f) State that upon the OPTN Contractor's receipt of the hearing request, the applicant or Member will be notified of the date, time, and place of the hearing.
- (3) **Request for Hearing:**
 - (a) Except in the case of Category I potential violations, an applicant or Member shall have 14 days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~.

- (b) Category I Potential Violations. In the case of Category I potential violations, an applicant or Member shall have seven days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) certified or registered mail.
- (4) **Waiver by Failure to Request a Hearing:** An applicant or Member who fails to request a hearing within the time and in the manner specified waives any right to such a hearing or any appellate review to which he might otherwise have been entitled. Such waiver in connection with:
- (a) An adverse action by the Board of Directors or the Executive committee, shall constitute acceptance of that action, which shall thereupon become effective as the final decision by the Board;
- (b) An adverse recommendation by the MPSC or the Executive committee shall constitute acceptance of that recommendation, which shall thereupon become and remain effective pending the final decision of the Board of Directors.
- (5) **Notice of Hearing:** Upon receipt of a timely request for a hearing, notification of the time, place, and date of the hearing shall be sent to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) certified mail at least 7 days prior to the hearing.
- (6) **Statement of Issues:** The notice of hearing described in Section 3.02A(5) above shall contain a concise statement of the issues raised by the adverse recommendation or action which is the subject of the hearing.
- (7) **Appointment of Hearing Committees:**
- (a) **By MPSC:** A hearing occasioned by an adverse MPSC recommendation shall be conducted by a hearing committee appointed by the chair of the MPSC and composed of three (3) members of the MPSC or in the discretion of the chair, shall be composed of those MPSC members who are in attendance at a regular or special MPSC meeting and are not disqualified under section 3.02A(8) below.
- (b) **By Board of Directors:** A hearing occasioned by an adverse action of the Board of Directors may be conducted by a hearing committee appointed by the chair of the Board of Directors and composed of three (3) directors. One of the appointees shall be designated as chair. Alternatively, in the discretion of the chair of the Board, the hearing shall be conducted by those Board Members who are in attendance at a regular or special meeting of the Board, provided that such Members are not disqualified under Section 3.02A(8) below and constitute at least a quorum of the full Board.
- (c) **By MPSC-PCSC or Ad Hoc MPSC Subcommittee/Executive Committee or Board in the Case of Category I Potential Violations:** A hearing occasioned by an adverse recommendation from a subcommittee of the MPSC or executive Committee or Board in the case of Category I potential violations shall be conducted by a hearing committee appointed by the chair and composed of at least three (3) members of the MPSC or, in the discretion of the chair, shall be composed of those members who are in attendance at a regular or special meeting and are not disqualified under section 3.02A(8) below, provided that such members constitute at least a quorum of the full committee or Board.

- (8) **Service on Hearing Committee:** A MPSC or Board of Directors member shall be disqualified from serving on a hearing committee if he/she has been personally and directly involved in compiling evidence for the OPTN Contractor on the matter at issue.
- (9) **Appearance and Representation:** Appearance by the applicant or Member who requested the hearing shall be required. An applicant or Member who fails without good cause to appear and proceed at such hearing shall be deemed to have waived his rights to such a hearing or any appellate review to which it might otherwise have been entitled. The applicant or Member may be represented by an attorney at any hearing or at any appellate review proceeding. The MPSC, MPSC subcommittee, Executive committee, or the Board of Directors shall be allowed representation by an attorney.
- (10) **Presiding Officer:** The chair of the hearing committee shall be the presiding officer. The presiding officer shall regulate the course of the hearing to assure that all participants in the hearing have a reasonable opportunity to present relevant oral and documentary evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts. He/she shall determine the order of procedure during the hearing and shall make all rulings on interpretation or construction of the OPTN Charter and Bylaws and other relevant documents and OPTN requirements on procedure; and on the admissibility of evidence. He/she shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence.
- (11) **Rights of Parties:** During a hearing, each of the parties shall have the right, subject to the presiding officer's rulings, to:
- (a) Call and examine witnesses;
 - (b) Introduce exhibits;
 - (c) Cross-examine any witness on any matter relevant to the issue;
 - (d) Impeach any witness;
 - (e) Rebut any evidence.

If the applicant or Member who requested the hearing does not testify in its own behalf, representatives of the application who are present may be called and examined as if under cross-examination.

- (12) **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. Any relevant matter upon which responsible persons customarily rely in the conduct of serious affairs shall be admitted, regardless of the admissibility of such evidence in a court of law. Each party shall, prior to or during the hearing, be entitled to submit memoranda concerning any issue, and such memoranda shall become part of the hearing record. The presiding officer may, but shall not be required to, order that oral evidence be taken only on oath or affirmation administered by any person designated by him/her and entitled to notarize documents in the state where the hearing is held.
- (13) **Official Notice:** In reaching a decision, the hearing committee may take official notice, either before or after submission of the matter for decision, of any generally accepted technical or scientific matter relating to the issues under consideration and of any facts that may be judicially noticed by the courts of the state where the hearing is held. Parties present at the hearing shall be informed of the matters to be thus noticed and those matters shall be noted in the hearing record. Any party shall be given opportunity, on timely request, to request that a matter be officially noticed and to refute the officially noticed matters by evidence or by written or oral presentation of authority, the manner of such refutation to be determined by the hearing committee. The committee shall also be entitled to consider all other information that can be considered, pursuant

to these Bylaws, in connection with applications for membership, applications for designation as a transplant program, or requests for corrective action.

- (14) **Burden of Proof:** The body whose adverse recommendation or action occasioned the hearing shall have the initial obligation to present evidence in support thereof, including an explanation of the action or recommendation and why it was taken. The applicant or Member who requested the hearing shall then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks any substantial factual basis or that such basis or the conclusions drawn therefrom are arbitrary, unreasonable, or capricious.
- (15) **Record of Hearing:** A record of the hearing shall be kept that is of sufficient accuracy to permit an informed and valid judgment to be made by any group that may later be called upon to review the record and render an appellate recommendation or decision in the matter. The hearing committee and the applicant or Member shall, by mutual agreement, select the method to be used for making the record such as court reporter, electronic recording unit, detailed transcription, or minutes of the proceedings. In the absence of mutual agreement, a court reporter shall be in attendance and shall prepare a written transcript. All exhibits admitted into evidence at the hearing and all memoranda submitted to the hearing committee before, during, or after the hearing, shall be incorporated in the record.
- (16) **Postponement:** Request for postponement of a hearing shall be granted by the hearing committee only upon a showing of good cause and only if the request therefor is made as soon as is reasonably practicable.
- (17) **Presence of Hearing Committee Members and Vote:** A majority of the hearing committee must be present throughout the hearing and deliberations. If a committee member is absent from any part of the proceedings, he/she shall not be permitted to participate in the committee's deliberations or the decision.
- (18) **Recesses and Adjournment:** The hearing committee may recess the hearing and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon conclusion of the presentation of oral and written evidence, the hearing shall be closed. The hearing committee shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon conclusion of its deliberations, the hearing shall be declared finally adjourned.
- (19) **Hearing Committee Report:** Following preparation of the hearing record, the hearing committee shall make a written report of its findings and recommendations in the matter and shall forward the same, together with the hearing record and all other documentation considered by it, to the body whose adverse recommendation or action occasioned the hearing. At the same time, a copy of the hearing committee report shall be forwarded to the applicant or Member. All findings and recommendations by the hearing committee shall be supported by reference to the hearing record. The presiding officer may extend the time for making the hearing committee's written report in his/her discretion by giving written notice to the participants.
- (20) **Action on Hearing Committee Report:** Following receipt of the report of the hearing committee, the MPSC, MPSC subcommittee, the Executive Committee, or the Board of Directors, as the case may be, shall consider the same and affirm, modify, or reverse its recommendation or action in the matter. It shall transmit a concise statement of the result and the reasons therefor, together with the hearing record, the report of the hearing committee, and all other documentation considered, to the Executive Director.
- (21) **Notice:** The Executive Director, or his/her designee, shall promptly send a copy of the result to the applicant or Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. A

copy of the result also shall be forwarded to the MPSC, Executive Committee, and/or to the Board of Directors in the event the applicant or Member exercises its rights to appellate review under Section 3.03A of the Bylaws. The applicant or Member may request that a copy of the hearing record and related documentation be furnished at the applicant's or Member's expense.

(22) **Effect of Favorable Result:**

- (a) **Adopted by the Board of Directors or Executive Committee:** If the Board of Directors' or Executive Committee's action is favorable to the applicant or Member, such action shall become the final decision of the Board and the matter shall be considered finally closed.
- (b) **Adopted by the MPSC:** If the MPSC's action is favorable to the applicant or Member, the Executive Director shall promptly forward it, together with all supporting documentation, to the Board of Directors for its final action. The Board shall take action thereon by adopting or rejecting the MPSC's action in whole or in part, or by referring the matter back to the MPSC for further consideration. Any such referral back shall state the reasons therefor, set a limit within which a subsequent recommendation to the Board must be made, and may include a directive that an additional hearing be conducted to clarify issues that are in doubt. After receipt of such subsequent recommendation and any new evidence in the matter, the Board shall take final action. The Executive Director shall promptly send the applicant or Member notice by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~, informing him/her of each action taken. Favorable action shall become the final decision of the Board of Directors, and the matter shall be considered finally closed. In the case of favorable action with respect to a Category I potential violation that has resulted in notice to the Secretary of HHS and/or public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and recommend restoration of unrestricted membership privileges to the Secretary of HHS. If the Board's action is adverse, the special notice shall inform the applicant or Member of his right to request an appellate review by the Board of Directors as provided in Section 3.03A below, unless the Board itself has conducted the hearing.

- (23) **Effect of Adverse Result:** If the result of the MPSC or of the Board of Directors or the Executive Committee continues to be adverse to the applicant or Member, the notice sent to him by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~, shall inform him of any applicable right to request an appellate review by the Board of Directors as provided in section 3.03A below.

3.03A - Appellate Review

(1) **Request for Appellate Review:**

- (a) Except in the case of Category I potential violations, in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, an applicant or Member shall have 14 days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. The applicant or Member may be represented during the appellate

review by an attorney. If the applicant or Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an appellate review.

- (b) **Category I Potential Violations.** In the case of Category I potential violations in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, a Member shall have seven days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. If the Board of Directors is the forum for the exercise of the Member's procedural rights, there is no right to Appellate Review and the decision of the Board is final. The Member may be represented during the appellate review by an attorney. If the Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the steps for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for an appellate review.
- (2) **Waiver by Failure to Request Appellate Review:** An applicant or Member who fails to request an appellate review within the time and manner specified in section 3.03A(1) above waives any right to such review.
- (3) **Notice of Time and Place for Appellate Review:**
- (a) Upon receipt of a timely request for appellate review, the Executive Director shall deliver such request to the Board of Directors. As soon as practicable, the Board shall schedule and arrange for an appellate review which, except in the case of Category I potential violations, shall be not less than 30 days from the date of receipt of the appellate review request. At least 25 days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.
- (b) **Category I Potential Violations.** In the case of Category I potential violations, the Board shall schedule and arrange for an appellate review not less than seven nor more than 30 days from the date of receipt of the appellate review request. At least five days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by facsimile or electronic transmission. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.
- (4) **Appellate Review Body:** The appellate review shall be conducted by the Board as a whole.

- (5) **Nature of Proceedings:** The proceedings by the review body shall be in the nature of an appellate review based upon the record of the hearing before the hearing committee, that committee's report, and all subsequent results and actions thereon. The appellate review body shall also consider any written or oral statements submitted by the applicant or Member, and its representative(s), if any, and any written or oral statements by the MPSC or the Board of Directors and any of their members, individually.
- (6) **Written Statements:** The applicant or Member seeking the review may submit a written statement detailing the findings of fact, conclusions, and procedural matters with which it disagrees, and the reasons for such disagreement. This written statement may cover any matters raised at any step in the hearing process, and legal counsel may assist in its preparation. The statement shall be submitted to the appellate review body through the Executive Director or his/her designee at least 15 days prior to the scheduled date of the appellate review, except if such time limit is waived or modified by the appellate review body. A written statement in reply may be submitted by the MPSC or by the Board of Directors, and if submitted, the Executive Director, or his/her designee, shall provide a copy thereof to the applicant or Member at least 5 days prior to the scheduled date of the appellate review or such shorter time as determined by the appellate review body.
- (7) **Presiding Officer:** The chair of the appellate review body shall be the presiding officer. He/she shall determine the order of procedure during the review, make all required rulings, and maintain decorum.
- (8) **Oral Statement:** The appellate review body, in its sole discretion, may allow the parties or their representatives to personally appear and make oral statements in favor of their positions. Any party or representative so appearing shall be required to answer questions put to him/her by any member of the appellate review body.
- (9) **Consideration of New or Additional Matters:** An applicant or Member may introduce at the appellate review matters or evidence related to steps taken after the conclusion of the original hearing to bring the applicant or Member into full compliance with membership qualifications or requirements. Other new or additional matters or evidence not raised or presented during the original hearing or in the hearing report and not otherwise reflected in the record shall be introduced at the appellate review only in the discretion of the appellate review body, following an explanation by the party requesting the consideration of such matter or evidence as to why it was not presented earlier. In the discretion of the appellate review body, new or additional matters or evidence permitted to be introduced at the appellate review may, but need not, be referred back to the hearing committee in accordance with section 3.03A(13) below.
- (10) **Powers:** The appellate review body shall have all the powers granted to the hearing committee, and such additional powers as are reasonably appropriate to the discharge of its responsibilities.
- (11) **Presence of Members and Vote:** A majority of the appellate review body must be present throughout the review and deliberations. If a member of the review body is absent from any part of the proceedings, he/she shall not be permitted to participate in the deliberations or the decision.
- (12) **Recesses and Adjournment:** The appellate review body may recess the review proceedings and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon the conclusion of oral statements, if allowed, the appellate review shall be closed. The appellate review body shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon the conclusions of those deliberations, the appellate review shall be declared finally adjourned.
- (13) **Action Taken:** The appellate review body may recommend affirmation, modification, or reversal the adverse result or action taken by the MPSC, by the Executive Committee or by a committee of

the Board or, in its discretion, may refer the matter back to the hearing committee for further review and recommendation to be returned to it in accordance with its instructions. After receipt of such recommendations after referral, the appellate review body shall make its decision as provided in this section. In the case of favorable action, which reverses an adverse result with respect to a Category I potential violation that has resulted in notice to the Secretary of HHS and/or public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and recommend restoration of unrestricted membership privileges to the Secretary of HHS.

- (14) **Conclusion:** The appellate review shall not be deemed to be concluded until all of the procedural steps provided herein have been completed or waived.

Final Decision of the Board of Directors

4.01A - Board of Directors Action

After the MPSC forwards a recommendation to the Board of Directors for which an applicant or Member waives the hearing and appellate review rights or after the conclusion of hearing and appellate review proceedings, the Board shall render its final decision in the matter (which, in the case of an appellate review proceeding, shall be the decision of the Appellate Review Body) in writing and shall send notice thereof to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~, and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the applicant or Member. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws.

If the Board should decide that a more serious sanction than the sanction recommended by the MPSC or Executive Committee is appropriate, the Board shall return the matter to the MPSC or Executive Committee, as the case may be, for its consideration of the imposition of the more serious sanction. If the MPSC or Executive Committee agrees with the Board, the more serious sanction shall be the final decision of the Board. If the MPSC or Executive Committee does not agree that the more serious sanction is appropriate, its initial recommendation to the Board shall be the final decision of the Board.

Notice of a final decision by the Board of Directors or Executive Committee that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of final decisions by the Board or Executive Committee to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendations by the Secretary.

Costs and Expenses

6.03A - Default in Payment of Reimbursable Cost and Expenses

Any applicant or Member who fails to pay reimbursable costs and expenses assessed pursuant to Section 6.01A within 30 days after having received notice by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~, at the applicant or Member's address as shown on the records of the OPTN Contractor, shall be referred to the Secretary for termination of either OPTN membership or further consideration of the application, as appropriate.

OPTN Bylaws, Appendix B

II. Transplant Hospitals

- A. General** [No changes]
B. Survival Rates [No changes]

C. Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. 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.

- 1. Functional Inactivity.** Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, “Functional Inactivity” is defined as any or all of the items below:

- (a) The inability to serve potential candidates, candidates, or recipients, for a period of 15 days or more consecutively;
- (b) failure to perform a transplant during the following stated periods of time:
 - i. In the case of kidney, liver, and heart transplant programs, within three consecutive months;
 - ii. In the case of pancreas and lung programs, within six consecutive months;
 - iii. In the case of stand-alone pediatric transplant hospitals, within twelve consecutive months.
- (c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.
- (d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

Any program identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

- (a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- (b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more 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 work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the 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 twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

2. Inactive Transplant Program Status. For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNetSM (short-term inactivation), or
- an inactive transplant program waiting list status in UNetSM and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

a. Short-Term Inactivation

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNetSM.

- i. **Notice to the OPTN Contractor.** 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.
- ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII each transplant program must provide potential candidates, candidates, and recipients with a written summary of its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b a. Long-Term Inactivation

Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days consecutively. Voluntary inactivation may extend for a period of up to 12 months.

- i. Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the OPTN Executive Director upon deciding to inactivate the transplant program.
- ii. Notice to the Patients.** When a Member intends to inactivate a transplant program for 15 or more days consecutively, it must provide:
 - a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be ~~provided mailed~~ at least 30 days prior to the anticipated inactivation date by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be ~~provided mailed~~ no later than seven days following inactivation and include:
 - 1) the reason(s) for inactivating the transplant program;
 - 2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
 - 3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

- 3. Transition Plan.** When the Member inactivates a transplant program for 15 or more days consecutively, it must:
 - a) promptly suspend organ implantation for that transplant program;
 - b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;

- c) provide a list to the OPTN contractor of all of the transplant program's candidates at the time of inactivation and update it throughout this process;
- d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
 - i) 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; or
 - ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
- e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another OPTN Member transplant hospital;
- f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive 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 for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.
- g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
 - i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, 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;
 - ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;
 - iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
 - iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;
 - v) for multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
 - vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.
 - vii) The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, 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 via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

4. **Extension of Voluntary Inactive Program Status Beyond Twelve Months.** A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.
5. **Reactivation after Voluntary Long Term Inactivation.** A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.
6. **Relinquishment or Termination of Designated Transplant Program Status.** Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is terminated by the Secretary of the Department of Health and Human Services ("Secretary"). 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 and/or the Executive Committee request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

- a. **Notice to the OPTN Contractor.** A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.
- b. **Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:
 - i) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated date of relinquishment or termination by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure

electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following relinquishment/termination and include:

1. the reason(s) for loss of designated transplant program status;
2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

- c. Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:
- i. promptly suspend organ implantation for the transplant program;
 - ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
 - iii. provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
 - iv. indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
 1. 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; or
 2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
 - v. 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;
 - vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. 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 the time periods within this section.

- vii. 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:
 - 1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, 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;
 - 2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
 - 3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
 - 4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
 - 5. for multi-visceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
 - 6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
 - 7. The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- ix. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care 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 via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

- 6. **Waiting time on waiting list.** To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.
- 7. **Laboratory Tests.** The inactivated program remains 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.

D – K [No further changes to this section]

UNOS Bylaws, Article I, Members

1.11 Removal of Non-Qualifying Members.

- a. Transplant center Institutional Members that fail to qualify as a UNOS Member under Article 1.2(b) shall be treated in accordance with Article II of Appendix B to these Bylaws.
- b. All other UNOS Members who cease to qualify for UNOS membership under Article I of these Bylaws may be removed as UNOS Members in accordance with the following procedures:
 1. The Member may request removal from UNOS membership by forwarding a written request therefor to UNOS, or
 2. Even if the Member does not request removal, UNOS may notify the Member in writing that, unless the Member demonstrates that it continues to meet applicable membership criteria within sixty (60) days of notification, the Member's UNOS membership will be terminated.
 - i. If, within sixty (60) days of such notification, the Member demonstrates, to the satisfaction of UNOS, that the Member continues to meet UNOS membership requirements, UNOS shall withdraw its notice of termination.
 - ii. If the Member fails to demonstrate that it continues to meet applicable UNOS membership requirements, its membership in UNOS will terminate on the sixtieth (60th) day after notification of termination by UNOS. The Member can appeal this decision to the Board of Directors. In the event a Member exercises this right of appeal, the Member shall notify UNOS of this exercise by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Board directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Board shall be submitted to the Membership and Professional Standards Committee as appropriate for action consistent with the Board's decision.
- c. Any Member that requests removal from UNOS membership or is otherwise removed from UNOS membership under this Article 1.11 may later re-apply for membership in accordance with Article 1.7 of these Bylaws.

- 1.12 Meetings.** The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Member Electors, Public Organization Member Electors, Medical/Scientific Member Electors, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to UNOS. Meetings of the UNOS membership typically shall be open to the public; however, discussions involving confidential matters including, UNOS member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be ~~provided mailed~~ provided to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

**Article II
Board of Directors**

- 2.6 Notice of Meetings.** Written notice of any regular or special meeting of the Board of Directors shall state the place, date and time of the meeting and shall be provided ~~mailed~~ to each Director at the address on file with the Executive Director not fewer than 10 or more than 60 days before the date of the meeting. The Executive Director shall circulate the agenda for each Board of Directors meeting to the Members at least 10 days prior to the meeting in order to promote input from the Members to the Directors. A written waiver of notice signed by a Director, whether before or after the time stated therein, shall be the equivalent of the giving of any notice required herein. A Director who attends a meeting shall be deemed to have had timely and proper notice thereof.

**Article X
Amendment of the Bylaws**

- 10.2 Notice.** Notice of any meeting at which an amendment to the By-Laws is proposed shall be provided ~~sent by mail~~ to each Director at the address on file with the Executive Director no fewer than 10 nor more than 60 days before the date of the meeting, accompanied by a copy of the proposed amendment.

**Appendix A to Bylaws
United Network for Organ Sharing
Corrective Action and Enforcement of UNOS Requirements
OPO, Transplant Hospital, and Histocompatibility Laboratory Members**

2.04A Requests

All requests for corrective action to enforce membership requirements shall be submitted to the MPSC in writing by the Executive Director or his/her designee, and shall be supported by reference to the specific activities or conduct which constitute the grounds for the request. The Executive Director, or his/her designee, shall promptly give notice of such request for corrective action to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested.~~

2.11A Procedural Rights

Procedural rights, including “interviews and hearings,” are further described in Section 3.01A – 3.03A of the Bylaws. If the member does not deliver a written request for an interview to the Chairperson of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ within 14 days following his receipt of such notice, the Member waives its rights to an interview and the MPSC may proceed to implement its proposed action.

**Appendix A to Bylaws
United Network for Organ Sharing
Interviews and Hearings**

3.01A Definition of “Adverse”

- (1) **Recommendations or Actions:** Subject to Section 3.01A(4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01A(2) below, entitle the applicant or member affected thereby to a hearing:
- (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of “Member Not in Good Standing” and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension; and
 - (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c) including, by way of example and not limitation, removal of designation as a transplant program.
- (2) **When Deemed Adverse:** A recommendation or action listed in Section 3.01A(1) above shall be deemed adverse only when it has been:
- (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or
 - (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.
- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSCPCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the

Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

- (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.
- (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:
 - (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested.~~, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to UNOS requirements);
 - (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director;
 - (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested.~~ (as well as facsimile transmission) if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense;

- (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members; and
- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

- (4) **Right to a Hearing:** An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review, with respect to any application for membership application for designation as a transplant program, or request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed on Section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in Section 3.03A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for a hearing and/or subsequent appellate review.

3.02A Hearings

- (1) **Parties:** The parties to a hearing shall be the applicant or Member against whom an adverse recommendation or action has been taken and the MPSC, the Executive Committee, or the Board of Directors, i.e., the body whose adverse recommendation or action is at issue.
- (2) **Notice of Adverse Recommendation or Action:** An applicant or Member against whom an adverse recommendation or action has been taken shall promptly be given notice of such action by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. Such notice shall:
 - (a) Briefly advise the applicant or Member of the nature of the adverse recommendation or action and the grounds therefor;
 - (b) Advise the applicant or Member of the right to a hearing pursuant to the provisions of these Bylaws;
 - (c) Specify the number of days following the date of receipt of notice within which a request for a hearing must be submitted;
 - (d) State that the failure to request a hearing within the specified time period shall constitute a waiver of rights to a hearing and to any appellate review of the matter;

- (e) State that all materials about the applicant or Member that were generated by or submitted to the MPSC, the Executive Committee or the Board, as the case may be, prior to that body's adverse recommendation or action, shall be made available to the applicant or Member, upon request, for inspection and copying; and
 - (f) State that upon UNOS' receipt of the hearing request, the applicant or Member will be notified of the date, time and place of the hearing.
- (3) **Request for Hearing:**
- (a) Except in the case of Category I potential violations, an applicant or member shall have 14 days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the Chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~; and
 - (b) **Category I Potential Violations.** In the case of Category I potential violations, an applicant or Member shall have seven days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~.
- (4) **Waiver by Failure to Request a Hearing:** An applicant or Member who fails to request a hearing within the time and in the manner specified waives any right to such a hearing or any appellate review to which he might otherwise have been entitled. Such waiver in connection with:
- (a) An adverse action by the Board of Directors or Executive Committee shall constitute acceptance of that action, which shall thereupon become effective as the final decision by the Board; and
 - (b) An adverse recommendation by the MPSC or Executive Committee shall constitute acceptance of that recommendation, which shall thereupon become and remain effective pending the final decision of the Board of Directors.
- (5) **Notice of Hearing:** Upon receipt of a timely request for a hearing, notification of the time, place, and date of the hearing shall be sent to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified mail~~ at least 7 days prior to the hearing.
- (6) **Statement of Issues:** The notice of hearing described in Section 3.02A(5) above shall contain a concise statement of the issues raised by the adverse recommendation or action which is the subject of the hearing.
- (7) **Appointment of Hearing Committees:**
- (a) **By MPSC:** A hearing occasioned by an adverse MPSC recommendation shall be conducted by a Hearing Committee appointed by the Chair of the MPSC and composed of three (3) members of the MPSC or in the discretion of the Chair, shall be composed of those MPSC members who are in attendance at a regular or special MPSC meeting and are not disqualified under Section 3.02A(8) below;

- (b) **By Board of Directors:** A hearing occasioned by an adverse action of the Board of Directors may be conducted by a Hearing Committee appointed by the Chair of the Board of Directors and composed of three (3) Directors. One of the appointees shall be designated as Chair. Alternatively, in the discretion of the chair of the Board, the hearing shall be conducted by those Board Members who are in attendance at a regular or special meeting of the Board, provided that such Members are not disqualified under Section 3.02A(8) below and constitute at least a quorum of the full Board; and
- (c) **By MPSC-PCSC or Ad Hoc MPSC Subcommittee/Executive Committee or Board in the Case of Category I Potential Violations:** A hearing occasioned by an adverse recommendation from a subcommittee of the MPSC or Executive Committee or Board in the case of Category I potential violations shall be conducted by a hearing committee appointed by the chair and composed of at least three (3) members of the MPSC or, in the discretion of the chair, shall be composed of those members who are in attendance at a regular or special meeting and are not disqualified under section 3.02A(8) below, provided that such members constitute at least a quorum of the full committee or Board.
- (8) **Service on Hearing Committee:** A MPSC or Board of Directors member shall be disqualified from serving on a Hearing Committee if he/she has been personally and directly involved in compiling evidence for UNOS on the matter at issue.
- (9) **Appearance and Representation:** Appearance by the applicant or Member who requested the hearing shall be required. An applicant or Member who fails without good cause to appear and proceed at such hearing shall be deemed to have waived his rights to such a hearing or any appellate review to which it might otherwise have been entitled. The applicant or Member may be represented by an attorney at any hearing or at any appellate review proceeding. The MPSC, MPSC subcommittee, Executive Committee, or the Board of Directors shall be allowed representation by an attorney.
- (10) **Presiding Officer:** The Chair of the Hearing Committee shall be the Presiding Officer. The Presiding Officer shall regulate the course of the hearing to assure that all participants in the hearing have a reasonable opportunity to present relevant oral and documentary evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts. He/she shall determine the order of procedure during the hearing and shall make all rulings on interpretation or construction of UNOS' Articles of Incorporation, Bylaws and other relevant document and UNOS requirements on procedure; and on the admissibility of evidence. He/she shall provide for the exclusion of irrelevant, immaterial or unduly repetitious evidence.
- (11) **Rights of Parties:** During a hearing, each of the parties shall have the right, subject to the Presiding Officer's rulings, to:
- (a) Call and examine witnesses;
 - (b) Introduce exhibits;
 - (c) Cross-examine any witness on any matter relevant to the issue;
 - (d) Impeach any witness; and
 - (e) Rebut any evidence.

If the applicant or member who requested the hearing does not testify in its own behalf, representatives of the application who are present may be called and examined as if under cross-examination.

- (12) **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. Any relevant matter upon which responsible persons customarily rely in the conduct of serious affairs shall be admitted, regardless of the admissibility of such evidence in a court of law. Each party shall, prior to or during the hearing, be entitled to submit memoranda concerning any issue, and such memoranda shall become part of the hearing record. The Presiding Officer may, but shall not be required to, order that oral evidence be taken only on oath or affirmation administered by any person designated by him and entitled to notarize documents in the state where the hearing is held.
- (13) **Official Notice:** In reaching a decision, the Hearing Committee may take official notice, either before or after submission of the matter for decision, of any generally accepted technical or scientific matter relating to the issues under consideration and of any facts that may be judicially noticed by the courts of the state where the hearing is held. Parties present at the hearing shall be informed of the matters to be thus noticed and those matters shall be noted in the hearing record. Any party shall be given opportunity, on timely request, to request that a matter be officially noticed and to refute the officially noticed matters by evidence or by written or oral presentation of authority, the manner of such refutation to be determined by the Hearing Committee. The committee shall also be entitled to consider all other information that can be considered, pursuant to these Bylaws, in connection with applications for membership, applications for designation as a transplant program, or requests for corrective action.
- (14) **Burden of Proof:** The body whose adverse recommendation or action occasioned the hearing shall have the initial obligation to present evidence in support thereof, including an explanation of the action or recommendation and why it was taken. The applicant or Member who requested the hearing shall then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks any substantial factual basis or that such basis or the conclusions drawn therefrom are either arbitrary, unreasonable, or capricious.
- (15) **Record of Hearing:** A record of the hearing shall be kept that is of sufficient accuracy to permit an informed and valid judgment to be made by any group that may later be called upon to review the record and render an appellate recommendation or decision in the matter. The Hearing Committee and the applicant or Member shall, by mutual agreement, select the method to be used for making the record such as court reporter, electronic recording unit, detailed transcription, or minutes of the proceedings. In the absence of mutual agreement, a court reporter shall be in attendance and shall prepare a written transcript. All exhibits admitted into evidence at the hearing and all memoranda submitted to the Hearing Committee before, during or after the hearing, shall be incorporated in the record.
- (16) **Postponement:** Request for postponement of a hearing shall be granted by the Hearing Committee only upon a showing of good cause and only if the request therefor is made as soon as is reasonably practicable.
- (17) **Presence of Hearing Committee Members and Vote:** A majority of the Hearing Committee must be present throughout the hearing and deliberations. If a Committee member is absent from any part of the proceedings, he shall not be permitted to participate in the Committee's deliberations or the decision.
- (18) **Recesses and Adjournment:** The Hearing Committee may recess the hearing and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon conclusion of the presentation of oral and written evidence, the hearing shall be closed. The Hearing Committee shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon conclusion of its deliberations, the hearing shall be declared finally adjourned.
- (19) **Hearing Committee Report:** Following preparation of the hearing record, the Hearing Committee shall make a written report of its findings and recommendations in the matter and shall

forward the same, together with the hearing record and all other documentation considered by it, to the body whose adverse recommendation or action occasioned the hearing. At the same time, a copy of the Hearing Committee Report shall be forwarded to the applicant or member. All findings and recommendations by the Hearing Committee shall be supported by reference to the hearing record. The Presiding Officer may extend the time for making the Hearing Committee's written report in his/her discretion by giving written notice to the participants.

- (20) **Action on Hearing Committee Report:** Following receipt of the report of the Hearing Committee, the MPSC, MPSC subcommittee, the Executive Committee, or the Board of Directors, as the case may be, shall consider the same and affirm, modify or reverse its recommendation or action in the matter. It shall transmit a concise statement of the result and the reasons therefor, together with the hearing record, the report of the Hearing Committee and all other documentation considered, to the Executive Director.
- (21) **Notice:** The Executive Director, or his/her designee, shall promptly send a copy of the result to the applicant or Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. A copy of the result also shall be forwarded to the MPSC, Executive Committee and/or to the Board of Directors in the event the applicant or Member exercises its rights to appellate review under Section 3.03A of the Bylaws. The applicant or Member may request that a copy of the hearing record and related documentation, be furnished at the applicant's or Member's expense.
- (22) **Effect of Favorable Result:**
- (a) **Adopted by the Board of Directors or Executive Committee:** If the Board of Directors' or Executive Committee's action is favorable to the applicant or Member, such action shall become the final decision of the Board and the matter shall be considered finally closed.
- (b) **Adopted by the MPSC:** If the MPSC's action is favorable to the applicant or Member, the Executive Director shall promptly forward it, together with all supporting documentation, to the Board of Directors for its final action. The Board shall take action thereon by adopting or rejecting the MPSC's action in whole or in part, or by referring the matter back to the MPSC for further consideration. Any such referral back shall state the reasons therefor, set a limit within which a subsequent recommendation to the Board must be made, and may include a directive that an additional hearing be conducted to clarify issues that are in doubt. After receipt of such subsequent recommendation and any new evidence in the matter, the Board shall take final action. The Executive Director shall promptly send the applicant or Member notice by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~, informing him of each action taken. Favorable action shall become the final decision of the Board of Directors, and the matter shall be considered finally closed. In the case of favorable action with respect to a Category I potential violation that the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice, thereof. If the Board's action is adverse, the special notice shall inform the applicant or member of his right to request an appellate review by the Board of Directors as provided in Section 3.03A below, unless the Board itself has conducted the hearing.
- (23) **Effect of Adverse Result:** If the result of the MPSC or of the Board of Directors or the Executive Committee continues to be adverse to the applicant or member, the notice sent to him by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt

~~requested) registered or certified mail, return receipt requested,~~ shall inform him of any applicable right to request an appellate review by the Board of Directors as provided in Section 3.03A below.

3.03A Appellate Review

(1) **Request for Appellate Review:**

(a) Except in the case of Category I potential violations, in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, an applicant or Member shall have 14 days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~ and may include a request for a copy of the report and record of the Hearing Committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. The applicant or Member may be represented during the appellate review by an attorney. If the applicant or Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an appellate review; and

(b) **Category I Potential Violations.** In the case of Category I potential violations in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, a Member shall have seven days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~ and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. If the Board of Directors is the forum for the exercise of the Member's procedural rights, there is no right to Appellate Review and the decision of the Board is final. The Member may be represented during the appellate review by an attorney. If the Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the steps for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for an appellate review.

(2) **Waiver by Failure to Request Appellate Review:** An applicant or Member who fails to request an appellate review within the time and manner specified in Section 3.03A(1) above waives any right to such review.

(3) **Notice of Time and Place for Appellate Review:**

(a) Upon receipt of a timely request for appellate review, the Executive Director shall deliver such request to the Board of Directors. As soon as practicable, the Board shall schedule and arrange for an appellate review, which, except in the case of Category I potential violations, shall be not less than 30 days from the date of receipt of the appellate review

request. At least 25 days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place and date of the review by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. The time for the appellate review may be extended by the Appellate Review Body for good cause and if the request therefor is made as soon as is reasonably practicable; and

- (b) **Category I Potential Violations.** In the case of Category I potential violations, the Board shall schedule and arrange for an appellate review not less than seven nor more than 30 days from the date of receipt of the appellate review request. At least five days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by facsimile or electronic transmission. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.
- (4) **Appellate Review Body:** The appellate review shall be conducted by the Board as a whole.
- (5) **Nature of Proceedings:** The proceedings by the review body shall be in the nature of an appellate review based upon the record of the hearing before the Hearing Committee, that committee's report, and all subsequent results and actions thereon. The Appellate Review Body shall also consider any written or oral statements submitted by the applicant or Member, and its representative(s), if any, and any written or oral statements by the MPSC or the Board of Directors and any of their members, individually.
- (6) **Written Statements:** The applicant or Member seeking the review may submit a written statement detailing the findings of fact, conclusions and procedural matters with which it disagrees, and the reasons for such disagreement. This written statement may cover any matters raised at any step in the hearing process, and legal counsel may assist in its preparation. The statement shall be submitted to the Appellate Review Body through the Executive Director or his/her designee at least 15 days prior to the scheduled date of the appellate review, except if such time limit is waived or modified by the Appellate Review Body. A written statement in reply may be submitted by the MPSC or by the Board of Directors, and if submitted, the Executive Director or his/her designee, shall provide a copy thereof to the applicant or Member at least 5 days prior to the scheduled date of the appellate review or such shorter time as determined by the appellate review body.
- (7) **Presiding Officer:** The Chair of the Appellate Review Body shall be the Presiding Officer. He/she shall determine the order of procedure during the review, make all required rulings, and maintain decorum.
- (8) **Oral Statement:** The Appellate Review Body, in its sole discretion, may allow the parties or their representatives to personally appear and make oral statements in favor of their positions. Any party or representative so appearing shall be required to answer questions put to him/her by any member of the Appellate Review Body.
- (9) **Consideration of New or Additional Matters:** An applicant or Member may introduce at the appellate review matters or evidence related to steps taken after the conclusion of the original hearing to bring the applicant or Member into full compliance with membership qualifications or requirements. Other new or additional matters or evidence not raised or presented during the original hearing or in the hearing report and not otherwise reflected in the record shall be introduced at the appellate review only in the discretion of the Appellate Review Body, following an explanation by the party requesting the consideration of such matter or evidence as to why it was not presented earlier. In the discretion of the Appellate Review Body, new or additional matters or evidence permitted to be introduced at the appellate review may, but need not, be referred back to the Hearing Committee in accordance with Section 3.03A(13) below.

- (10) **Powers:** The Appellate Review Body shall have all the powers granted to the Hearing Committee, and such additional powers as are reasonably appropriate to the discharge of its responsibilities.
- (11) **Presence of Members and Vote:** A majority of the Appellate Review Body must be present throughout the review and deliberations. If a member of the Review Body is absent from any part of the proceedings, he/she shall not be permitted to participate in the deliberations or the decision.
- (12) **Recesses and Adjournment:** The Appellate Review Body may recess the review proceedings and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon the conclusion of oral statements, if allowed, the appellate review shall be closed. The Appellate Review Body shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon the conclusions of those deliberations, the appellate review shall be declared finally adjourned.
- (13) **Action Taken:** The appellate review body may recommend affirmation, modification, or reversal the adverse result or action taken by the MPSC, by the Executive Committee or by a committee of the Board or, in its discretion, may refer the matter back to the hearing committee for further review and recommendation to be returned to it in accordance with its instructions. After receipt of such recommendations after referral, the appellate review body shall make its decision as provided in this section. In the case of favorable action, which reverses an adverse result with respect to a Category I potential violation that has resulted in notice to the public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and restoration of unrestricted membership privileges.
- (14) **Conclusion:** The appellate review shall not be deemed to be concluded until all of the procedural steps provided herein have been completed or waived.

**Appendix A to Bylaws
United Network for Organ Sharing
Final Decision of Board of Directors**

4.01A Board of Directors Action

After the MPSC forwards a recommendation to the Board of Directors for which an applicant or Member waives the hearing and appellate review rights or after the conclusion of hearing and appellate review proceedings, the Board shall render its final decision in the matter (which, in the case of an appellate review proceeding, shall be the decision of the Appellate Review Body) in writing and shall send notice thereof to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws. If the Board should decide that a more serious sanction than the sanction recommended by the MPSC or Executive Committee is appropriate, the Board shall return the matter to the MPSC or Executive Committee, as the case may be, for its consideration of the imposition of the more serious sanction. If the MPSC or Executive Committee agrees with the Board, the more serious sanction shall be the final decision of the Board. If the MPSC or Executive Committee does not agree that the more serious sanction is appropriate, its initial recommendation to the Board shall be the final decision of the Board. Notice of a final decision by the Board of Directors or Executive Committee that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members.

**Appendix A to Bylaws
United Network for Organ Sharing
Costs and Expenses**

6.03A - Default in Payment of Reimbursable Cost and Expenses

Any applicant or Member who fails to pay reimbursable costs and expenses assessed pursuant to Section 6.01A within 30 days after having received notice by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~, at the applicant or Member's address as shown on the records of UNOS, shall be referred for termination of either UNOS membership or further consideration of the application, as appropriate.

**APPENDIX B TO BYLAWS
UNITED NETWORK FOR ORGAN SHARING**

II. Transplant Hospitals

C. Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. 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.

- 1. Functional Inactivity.** Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "Functional Inactivity" is defined as any or all of the items below:

- (a) The inability to serve potential candidates, candidates, or recipients, for a period of 15 days or more consecutively;
- (b) failure to perform a transplant during the following stated periods of time:
 - i. In the case of kidney, liver, and heart transplant programs, within three consecutive months;
 - ii. In the case of pancreas and lung programs, within six consecutive months;
 - iii. In the case of stand-alone pediatric transplant hospitals, within twelve consecutive months.
- (c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.
- (d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and

Any programs identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

- (a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- (b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more 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 work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the 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 twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

2. Inactive Transplant Program Status. For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNetSM (short-term inactivation), or
- an inactive transplant program waiting list status in UNetSM and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

a. Short-Term Inactivation

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNetSM.

- i. **Notice to UNOS.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the UNOS.
- ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII transplant program must provide potential candidates, candidates, and recipients with a written summary of its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b. Long-Term Inactivation

Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days. Voluntary inactivation may extend for a period of up to 12 months.

- i. **Notice to UNOS.** When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the UNOS Executive Director upon deciding to inactivate the transplant program.
- ii. **Notice to the Patients.** When a Member intends to inactivate a transplant program for 15 or more days consecutively, it must provide:
 - a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated inactivation date by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following inactivation and include:
 - 1) the reason(s) for inactivating the transplant program;
 - 2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
 - 3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the patient notice to UNOS along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

3. **Transition Plan.** When the Member inactivates a transplant program for 15 or more days consecutively, it must:
- a) promptly suspend organ implantation for that transplant program;
 - b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
 - c) provide a list to UNOS of all of the transplant program's candidates at the time of inactivation and update it throughout this process;
 - d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
 - i) 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; or
 - ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
 - e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another UNOS Member transplant hospital;
 - f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive 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 UNOS all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.
 - g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
 - i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, 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;
 - ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;
 - iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
 - iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;
 - v) for multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
 - vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.

- vii) The program must document and submit to UNOS all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- i) remove every transplant candidate from the inactive transplant program’s waiting list within 12 months of the program’s inactivation date in the cases when a program does not intend to reactivate.
Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, 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 via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

4. Extension of Voluntary Inactive Program Status Beyond Twelve Months. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC’s satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

5. Reactivation After Voluntary Long Term Inactivation. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

6. Relinquishment or Termination of Designated Transplant Program Status: Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to UNOS. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member’s designated program status is terminated by the Secretary of the Department of Health and Human Services (“Secretary”). 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 and/or the Executive Committee request approval from the Secretary to terminate a Member’s designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program’s candidates to another transplant program.

- a. **Notice to the UNOS.** A Member transplant hospital must provide written notice to UNOS within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

- b. Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:
- i) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated date of relinquishment or termination by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following relinquishment/termination and include:
 1. the reason(s) for loss of designated transplant program status;
 2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
 3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to UNOS along with a list of potential candidate, candidate, and recipient names who received the notice.

- c. Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:
- i. promptly suspend organ implantation for the transplant program;
 - ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
 - iii. provide a list to UNOS of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
 - iv. indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
 1. 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; or
 2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

- v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another UNOS Member transplant hospital;
 - i. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. 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 UNOS all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.
 - ii. 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:
 - 1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, 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;
 - 2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
 - 3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
 - 4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
 - 5. for multivisceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
 - 6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
 - 7. The program must document and submit to UNOS all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
 - i. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
 - ii. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care 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 via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

6. **Waiting time on waiting list.** To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.
7. **Laboratory Tests.** The inactivated program remains 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.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.