

## At-a-Glance

- **Proposal to Add Language to the OPTN/UNOS Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts**
- **Affected/Proposed Policy/Bylaws:**
  - **Bylaws, Article I, Section 1.10 (Member Obligations)**
  - **Appendix B to Bylaws, Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, Section I (Organ Procurement Organizations) and Section II (Transplant Hospitals)**
  - **Policy 3.4: (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation)**

- **Membership and Professional Standards Committee (MPSC)**

- This proposal adds language to the bylaws stipulating that members are obligated to follow their respective state laws regarding anatomical gifts. This bylaw will ultimately help preserve public trust in the national organ transplant system by preventing conflicts of interest associated with having the same person declare death and perform organ procurement and transplantation. The ultimate goal of this proposed change is to prohibit the same physician from declaring a patient's death and participating in the removal or transplant of organs from that decedent.

- **Affected Groups:**

OPO staff  
Transplant program directors  
Surgeons  
Administrators  
Physicians  
General Public

- **Specific Requests for Comment**

Does this proposal to amend the bylaws and policies clearly inform members that they are obligated to follow their respective state laws regarding anatomical gifts?

**Please note**, additional modifications to Sections I and II of the OPTN and UNOS Bylaws are also out for public comment. The proposed language does not reflect suggested modifications relating to the *“OPTN notification requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs when faced with an adverse action taken by regulatory agencies”* proposal.

## **Proposal to Add Language to the OPTN/UNOS Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts**

- **Affected/Proposed Policy/Bylaws:**
  - **Bylaws, Article I, Section 1.10 (Member Obligations)**
  - **Appendix B to Bylaws, Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, Section I (Organ Procurement Organizations) and Section II (Transplant Hospitals)**
  - **Policy 3.4: Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation.**

### **Membership and Professional Standards Committee (MPSC)**

#### **Summary and Goals of the Proposal:**

This proposal adds language to the bylaws that stipulates that members are obligated to follow their respective state laws regarding anatomical gifts. This bylaw will ultimately help to preserve public trust in the national organ transplant system by preventing conflicts of interest regarding declaration of death, organ procurement and transplantation being performed by the same person. The ultimate goal of this proposed change is to prohibit the same physician from declaring a patient's death and participating in the removal or transplant of organs from that decedent.

#### **Background and Significance of the Proposal:**

During its meetings in May and July 2008, the MPSC discussed an issue discovered during a committee-directed peer visit. During their review, the peer team noted concerns relating to a single surgeon who had been involved in the declaration of death in organ donors, and was subsequently also involved in the procurement and transplantation of their organs. The team informed the center at the end of the visit of the potential conflict this practice presents and reported its concerns to the MPSC.

The MPSC discussed the issue at length on May 7, 2008, and referenced the Revised Uniform Anatomical Gift Act of 2006 (UAGA), Section 14, Part I:

*Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent.*

The UAGA further defines Anatomical Gift as *"a donation of all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education."*

While the OPTN Policy 2.2.1 states that the host Organ Procurement Organization (OPO) is responsible for verifying that potential donor death has been pronounced according to applicable laws, there was no OPTN bylaw that specifically prohibited a physician from declaring death and then later participating in procuring and transplanting those organs or tissues. The Committee agreed that the OPTN needed to amend the policies and bylaws to address the points made in the UAGA and to require surgeons who were involved in declaration of donor death to not be involved in organ procurement and transplantation. The MPSC appointed a subcommittee to hasten this review. The Subcommittee met by conference call in September 2008, and agreed to develop a proposal for the full MPSC to consider.

During the October 2008 MPSC meeting, the subcommittee presented a draft proposal describing how to modify the policies. This proposal outlined detailed requirements and the roles of physicians in the brain death declaration, organ procurement, and transplant process. The MPSC agreed that the Ethics and OPO Committees should weigh in on the proposal before it considered it further. Both the Ethics and OPO Committees reviewed the proposal and agreed that the first draft of the policy proposal was too complex and suggested that the MPSC reconsider its approach.

The Committee agreed it could achieve the same goal by amending the bylaws and policies to require transplant center and OPO members to follow their respective state laws regarding anatomical gifts. The OPTN may conduct reviews and evaluations of the members, and those who are found to be non-compliant will be handled in a manner described in Appendix A of the Bylaws. This approach would allow the committee to consider actions against a transplant center that appears to have violated the policy. The present requirements only give the OPTN the option of making an adverse recommendation against an OPO when the OPO fails to verify that potential donor death was pronounced according to applicable laws. The Committee considered amending the bylaws only to reference the UAGA but that was not found to be a practical option since the states have enacted different versions of the UAGA.

- ***Strengths and weaknesses:***

A strength of the proposal is that it explicitly states the OPTN’s expectation that transplant center and OPO members will be held responsible for following their own state law regarding anatomical gifts. These laws define a clear separation between the different roles and obligations of the OPO, the transplant surgeon and physician, and the primary physician for the donor. The proposal also clearly states what will happen if the member fails to comply. No specific weaknesses are identified in this proposal.

- ***Description of intended and unintended consequences:***

The proposal makes it clear that all members are accountable for complying with their applicable state laws. We do not expect this bylaw change to place an undue burden on transplant centers or OPOs since they should already be in compliance with their state laws.

**Supporting Evidence and/or Modeling:**

The MPSC encountered an issue between an OPO and one of its transplant programs regarding a potential conflict of interest. During the investigation, it was discovered that there were no bylaws or policies that applied to transplant programs to address the potential conflict of interest. Additionally, the OPO was unable initially to convince the transplant program that there was indeed the potential for a perceived conflict of interest. Though the issue has since been resolved, the committee agreed that further clarification was warranted in the bylaws to eliminate this from recurring.

**Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
<b>Maximum Capacity</b>	The OPTN will support the HHS Program Goals and maximize the number of donors and transplants
<b>Operational Effectiveness</b>	The OPTN will identify process and system

improvements that best support critical network functions, and work to disseminate them to all members who could benefit

**Plan for Evaluating the Proposal:**

- **What questions or hypotheses are guiding the evaluation of the proposal?**

The policy was always implied with the UAGA, but the 2008 situation mentioned above identified the need for the OPTN to formalize a policy regarding the importance of separating duties.

The public may lose trust in the organ donation process if they perceive that physicians taking care of sick patients also have an interest in obtaining their organs or tissues for transplantation. The policy will give the OPTN the power to take action against centers whose physicians participate in managing the sick patient, declaring death, and are subsequently involved in procuring or transplanting the organs or tissues from the decedent.

- **Policy Performance Measures:**

- No specific data are required. It is illegal and inconsistent with widely accepted principles of professional behavior, as indicated by the UAGA, for physicians to be involved in terminal care of the decedent and/or declaration of death and organ procurement in the same patient. Hence, this activity rarely occurs; however, experience with a center where this did occur highlighted a situation where the MPSC recognized a problem but had no power to take action to modify the situation.
- Violations will come to the MPSC’s attention by reports, such as those compiled by UNOS site auditors or peer review site visit teams, without the need to monitor data.

- **Time Line for Evaluation:** The Committee will review any instances of non-compliance once notification of an event or practice has been received. The bylaws and policy will be evaluated as applied to determine if it is achieving the stated goals.

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

Transplant centers and OPOs will need to review their current practices to ensure that they are in compliance with their state laws regarding anatomical gifts.

This proposal will not require programming in UNet<sup>SM</sup> or the Membership Database.

**Communication and Education Plan:**

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
UNOS Update announcement	All UNOS Members and the transplant	Electronic, Paper	Next edition of Update after

	community		passage by the Board of Directors
Implementation Notice	All UNOS Members and the transplant community	Electronic	Immediately after passage (30-days)

**Monitoring and Evaluation:**

Host OPOs, Transplant Centers, surgeons, and physicians will be expected to comply with the bylaws and policy. The UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance.

DEQ staff may detect potential violations of this proposed policy by:

- verifying the presence of written procedures to support this policy during reviews of OPOs and transplant centers
- researching self-reports of potential policy violations
- gathering information through discussions conducted during reviews of OPOs and transplant centers
- researching confidential reports of complaints received through the OPTN Member Reporting Line or Patient Services Line
- reviewing OPTN data
- receiving referrals from OPTN/UNOS Committees, UNOS Staff, OPTN/UNOS Members, or the public

UNOS staff forwards potential policy violations to the Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

The conduct and privileges of a physician at a transplant center are detailed by the medical staff office where the physician practices. The OPTN could also verify that the medical staff office of each transplant center has this final document.

## Bylaw and Policy Proposal:

### OPTN Bylaws

#### OPTN BYLAWS, ARTICLE I

##### MEMBERS

**1.10 Member Obligations.** By accepting membership in the OPTN, each Member agrees to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; OPTN Final Rule, 42 CFR Part 121; its respective state laws regarding anatomical gifts; these Bylaws; and OPTN policies as in effect from time to time. The OPTN will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with the OPTN Final Rule and OPTN policies. All OPTN Members are subject to review and evaluation for compliance with OPTN policies. All such compliance monitoring is performed using processes and protocols developed by the OPTN Contractor in accordance with the OPTN Contract. The failure of an organ procurement organization Institutional Member, independent Histocompatibility laboratory Institutional Member, Medical/Scientific Member, Public Organization Member, Business Member, or Individual Member to qualify as an OPTN Member according to the administrative requirements under Articles 1.2 – 1.6 of these Bylaws (*e.g.*, an organ procurement organization that ceases to be designated under Section 1138(b) of the Social Security Act) shall be dealt with in accordance with Article 1.11 of these Bylaws.

**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 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.

## **APPENDIX B TO BYLAWS OPTN**

### **Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

#### **I. Organ Procurement Organizations:**

**General.** An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; its respective state laws regarding anatomical gifts ; these Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each OPO shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur:

- (1) an adverse action that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and
- (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee that would impose a significant limitation upon the OPO's ability to procure organs.

[No further changes to this section]

#### **II. Transplant Hospitals.**

- A. General.** A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in the OPTN.

Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; its respective state laws regarding anatomical gifts; these Bylaws; and OPTN policies.

Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

For each of its organ-specific transplant programs, a Transplant Hospital shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur:

- (1) an adverse action that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of eligibility and any threatened or actual termination of eligibility; and
- (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee (e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients.

[No further changes to this section]

## UNOS Bylaws and Policies

### UNOS BYLAWS, ARTICLE I

#### MEMBERS

- 1.10 Member Obligations.** By accepting membership in UNOS, each Member agrees to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; OPTN Final Rule, 42 CFR Part 121; its respective state laws regarding anatomical gifts; these Bylaws; and UNOS policies as in effect from time to time. UNOS will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with the OPTN Final Rule and UNOS policies. All UNOS Members are subject to review and evaluation for compliance with UNOS policies. All such compliance monitoring is performed using processes and protocols developed by UNOS in accordance with the OPTN Contract. The failure of an organ procurement organization Institutional Member, independent histocompatibility laboratory Institutional Member, Medical/Scientific Member, Public Organization Member, Business Member, or Individual Member to qualify as a UNOS Member according to the administrative requirements under Articles 1.2 – 1.6 of these Bylaws (e.g., an organ procurement organization that ceases to be designated under Section 1138(b) of the Social Security Act) shall be dealt with in accordance with Article 1.11 of these Bylaws.



### **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 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.

## **APPENDIX B TO BYLAWS**

### **UNITED NETWORK FOR ORGAN SHARING**

#### **I. Organ Procurement Organizations.**

**General.** An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social

Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; its respective state laws regarding anatomical gifts; these Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each OPO shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur:

- (1) an adverse action that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and
- (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee that would impose a significant limitation upon the OPO's ability to procure organs.

[No further changes to this section]

## II. Transplant Hospitals.

- A. General.** A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in the OPTN.

Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; its respective state laws regarding anatomical gifts; these Bylaws; and OPTN policies.

Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

For each of its organ-specific transplant programs, a Transplant Hospital shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur:

- (1) an adverse action that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of

- eligibility and any threatened or actual termination of eligibility; and
- (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee (e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients.

[No further changes to this section]

**Proposed Change to Policy**

**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.

**3.4.1 Avoidance of Conflicts of Interest.** Neither the attending physician of the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedure for removing or transplanting an organ from the decedent. For purposes of this section, "organ" is defined as set forth in the OPTN Final Rule (42 C.F.R Part 121.2), and "decedent" is defined as a deceased individual whose body is or may become the source of a donated organ.

[Following sections renumbered only]

**3.4.12 Time Limit For Acceptance.....**

**3.4.23 Multiple Organ Retrieval.....**

**3.4.34 Department of Defense Directive.....**

**3.4.45 Multiple Organs Offer. ....**

**3.4.56 National Distribution of Organs.**

**3.4.67 Receiving and Responding to Organ Offers....**

**3.4.78 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.....**

- 3.4.7-18.1 Application**
- 3.4.7-28.2 Data Submission Requirements**
- 3.4.7-3-8.3 Dissolution of Alternative Assignment Systems**
- 3.4.7-4 8.4 Modifications of Alternative Point Assignment Systems, Sharing Arrangements and ALUs.**
- 3.4.7-58.5 AAD Systems Approved Prior to March 15, 2005**

**3.4.89 Application, Review, Dissolution and Modification Processes for Variances.....**

- 3.4.8-1 9.1 Application**
- 3.4.8-2 9.2 Data Requirements.**
- 3.4.8-3 9.3 Appeal to Secretary.**
- 3.4.8-4 9.4 Termination of Member Participation in Variance.**

~~3.4.8.5~~ 9.5 Modification of Variance.

**3.4.910** Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems....

~~3.4.9.1~~ 10.1 Development and Application.

~~3.4.9.2~~ 10.2 Data Requirements.

~~3.4.9.3~~ 10.3 Termination of Member Participation in Committee-Sponsored Alternative System.

~~3.4.9.4~~ 10.4 Modification of Committee-Sponsored Alternative System.

~~3.4.9.5~~ 10.5 Committee-Sponsored Alternative Systems Approved Prior to March 15, 2005.

**3.4.1011** Allocation of Organs During Regional/National Emergency Situations.....

~~3.4.10.1~~ 11.1 Regional/National Transportation Disruption.

~~3.4.10.2~~ 11.2 Regional/National Communications Disruption.

~~3.4.10.3~~ 11.3 Operational Disruption.