At-a-Glance

- **OPTN Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies**

- **Affected Bylaws: Appendix B (Sections I, II, III): Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

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

  The purpose of this bylaw modification is to clarify member responsibilities with regard to OPTN notification of adverse actions taken by regulatory agencies that would impact the organization's ability to serve transplant patients. The Committee modified existing language within the bylaws to clarify material submission and extend time periods for action.

- **Affected Groups**

  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  Transplant Administrators
  Transplant Program Directors

- **Specific Requests for Comment**

  Please feel free to comment on the entire document in addition to the following questions:
  1. Does this proposal further clarify notification requirements, including materials required as part of the notification?
  2. Is the modified time period for reporting this type of action less burdensome to members?

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 *"Avoiding Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement"* proposal.

OPTN Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies

Affected Bylaws: Appendix B (Sections I, II, III): Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

The MPSC suggested modifying the bylaws that currently require a member to notify the OPTN within 5 business days when a final adverse action is taken by a regulatory agency (or its designee). The proposed change would extend the notification period to 10 business days. The intent of this modification is to minimize the burden on OPOs, Transplant Hospitals, and Histocompatibility Labs by extending the length of time for reporting the action; removing the requirement to submit all materials relating to the issue; and only requiring notification when the adverse action is final.

The current bylaws require members to notify the OPTN of any threatened or real adverse action, including submission of all materials relating to the issue, within five (5) days. The existing bylaw language was approved by the Board of Directors in June 2006, concurrent with public comment. At that time, and of particular interest now, the Centers for Medicare and Medicaid Services (CMS) process for transplant program approval had not been finalized. The MPSC is aware that there are transplant programs that have not met CMS Conditions of Participation and that have applied for CMS approval based on mitigating factors. The existing bylaws require members in this situation to notify the OPTN, though few have done so. The Committee, recognizing that the CMS approval process may take several months and may require multiple submissions of supporting documentation, recommends that the bylaws be modified to only require OPTN notification of final adverse action(s).

Though CMS is referenced, it should be noted that these requirements relate to any state or federal regulatory agency or its designee.

- ***Alternatives considered:*** The MPSC considered striking the language from all relevant sections of the bylaws completely. Ultimately, the Committee agreed to modify the language instead, as the adverse actions taken by other agencies may be relevant to the MPSC's monitoring and evaluation efforts.

- ***Strengths and weaknesses:*** The MPSC hopes that this modification will enhance member compliance with bylaws without placing additional burden on the member.

- ***Description of intended and unintended consequences****:* This bylaw change is expected to reduce member burden by only requiring submission of documents pertinent to the final adverse actions taken by a regulatory agency. Additionally, members will be allotted additional time to notify the OPTN of final adverse actions.

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

HHS Program Goals	*Strategic Plan Goals*
Patient Safety	The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors

This bylaw modification, while minimizing member burden, will further support the MPSC's evaluation and monitoring efforts to promote safe, high-quality care for transplant patients.

Plan for Evaluating the Proposal:

The MPSC will evaluate the bylaw modification as part of its routine performance monitoring initiatives, considering the burden placed on the member. The Bylaw modification reduces the types of documents that must be sumbitted and extends the time period for OPTN notification. The Committee anticipates that this modification will also reduce the MPSC workload through improved member compliance. No specific data will be needed to evaluate the proposal. The bylaw will be evaluated on an ongoing basis to determine if it is achieving the stated goals.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

OPOs, Transplant Hospitals, and Histocompatibility Labs must submit to the OPTN, within 10 business days, letters of adverse actions taken by regulatory agencies. To meet this requirement, when notified of the final adverse action, the member must submit a copy of the initial notice of potential action and the final determination from the regulatory agency.

This proposal will not require programming in UNet^{SM}.

Communication and Education Plan:

There will be multiple communications regarding these bylaws. First, the MPSC recommended notifying all OPTN Members of the existing bylaw requirement before the proposed modifications were distributed for public comment. UNOS distributed this communications electronically on May 22, 2009 to all OPO Executive and Medical Directors, Histocompatibility Lab Directors, Transplant Program Directors and Administrators, as well as designated OPTN/UNOS Representatives and included what must be submitted to meet the existing bylaws. The communication also stated that the bylaws have been recommended for modification and are available for public comment.

If this proposal to amend the bylaws is approved, a policy notice announcing the final bylaw language will be distributed to the same group.

Communication Activities			
Type of Communication	**Audience(s)**	**Delivery Method(s)**	**Timeframe**
Policy Notice Reminder – Existing Bylaw Language	OPO Executive and Medical Directors Lab Directors Transplant Administrators Transplant Program Directors OPTN/UNOS Representative	Electronic	Distributed May 22, 2009
Policy Notice – Modified Bylaw Language		Electronic	Within 30 days of Board Approval

Monitoring and Evaluation:

Compliance with this bylaw will be monitored by the MPSC. The Committee anticipates that this modification will improve compliance. Instances where members do not inform the OPTN of adverse action within 10 days will be considered by the MPSC, and/or its Subcommittees as discovered.

Policy or Bylaw Proposal: Please note, additional modifications to Sections I and II of the OPTN and UNOS Bylaws are also out for public comment. The language below does not reflect suggested modifications relating to the "*Avoiding Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement"* proposal.

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; 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 in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur:~~

~~(1)~~ an adverse action has been taken against it ~~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; 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 in writing within ~~five (5)~~ 10 business days~~, to include copies of all related correspondence or reports,~~ when an adverse action related to any of its transplant programs has been taken ~~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]

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws.

Additionally, Histocompatibility Laboratories 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; these Bylaws; and OPTN policies.

Histocompatibility Laboratories 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 Histocompatibility Laboratory shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur:~~

~~1)~~ an adverse action has been taken against it ~~that leads to or threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; 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 laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients~~.

[No further changes to this section]

APPENDIX B TO BYLAWS
UNITED NETWORK FOR ORGAN SHARING

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; 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 in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur: (1)~~ an adverse action has been taken against it ~~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; 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~~

A Transplant Hospital shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur: (1)~~ an adverse action related to any of its transplant programs has been taken ~~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]

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws. Additionally, Histocompatibility Laboratories 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; these Bylaws; and OPTN policies.

Histocompatibility Laboratories 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 Histocompatibility Laboratory shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur: 1~~) an adverse action has been taken against it ~~that leads to or threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; 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 laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients~~.

[No further changes to this section]