

At-a-Glance

- **Proposal to change the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel**
- **Bylaws affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel)**

- **Membership and Professional Standards Committee**

This proposal to change the bylaws will clarify when transplant centers must notify UNOS of changes in key personnel and further clarifies that member institutions that cannot comply with this bylaw should voluntarily inactivate or withdraw the affected transplant program. This proposed language places greater emphasis on the submission of complete applications. Additionally, it clarifies the steps that will be taken if the member fails to inform the OPTN Contractor of key personnel changes.

- **Affected groups**

Primary transplant surgeons, primary transplant physicians, transplant program directors, transplant administrators.

- **Specific requests for comment**

- Does this proposal clearly address when transplant centers must report key personnel changes to the OPTN by describing
 - What a center needs to do if a key person ceases to participate in a program;
 - What a center needs to do if a key person remains involved but their responsibilities in the program have changed?
- Does the proposal make it clear that the program is expected to submit a complete application within 30-days of a key personnel change?
- Does the proposal clearly point out that a program should be inactivated or withdrawn if it is unable to demonstrate that it has key personnel who meet program approval requirements?
- Does the proposal adequately inform the member of the steps that will be taken if the member fails to inform the OPTN Contractor of changes in key personnel?

Proposal to change the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel.

Bylaws affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel)

Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

This proposal to change the bylaws will clarify when transplant centers must notify UNOS of changes in key personnel and further clarifies the expectation that member institutions that cannot notify UNOS within the expected time frame should voluntarily inactivate or withdraw the affected programs. This proposed language places greater emphasis on submitting complete applications. Additionally, it informs the member of the steps that will be taken if the member fails to inform the OPTN Contractor of changes in key personnel.

The MPSC identified the following goals while developing this proposal:

- Minimize the time a center takes to submit a change in key personnel application when an individual is no longer available to the program.
- Inform programs that they must submit complete Key Personnel Change Applications in at least 30 days or no later than 30 days prior to the key personnel change taking place.
- Insure that transplant programs have qualified personnel in key positions continuously.
- Clarify that centers must inactivate or withdraw programs that do not meet key personnel requirements.

Background and Significance of the Proposal:

At its November 13-14, 2007 meeting, the MPSC formed a work group to address committee goals. In particular, the work group needed to review the efficiency and effectiveness of currently used member qualification assessment methods and recommend improvements to the process. The Work Group was asked to consider whether or not the current level of program review is adequate to ensure ongoing compliance and competency, and if there were areas that could be improved.

The Work Group identified several areas of concern in the existing bylaws related to changes in key personnel:

- Members are unaware of the notification requirements in the bylaws and do not routinely notify the OPTN/UNOS immediately when they experience a change in key personnel.
- Members do not consistently submit completed key personnel change applications within 30-days of a change in key personnel.
- The majority of applications submitted are missing required information or documentation. It often takes months for members to supply follow up information as requested by staff or the MPSC so that they can be resolved. Some applications remain open or unresolved for extended periods in the review process. This delay increases the potential risk to patient safety, since the center has not demonstrated that it is staffed with individuals who meet the key personnel requirements.

- Centers that do not have a surgeon or physician on site who meets the key personnel requirements will submit applications naming unqualified individuals, seemingly in order to “buy time” while they recruit qualified individuals.
- Members seemingly presume that once an individual has been named in any application that they have been “UNOS certified” and that they don’t need to submit any new information regarding the individual’s ability to meet the requirements.

The Work Group suggested that the MPSC change the bylaw language regarding time limits for notifying and submitting applications to UNOS about changes in key personnel. The MPSC agreed that these changes will allow more timely oversight of the notification process and allow it to readily address the concern that some applications are drawn out for long periods because the centers do not submit complete information initially.

The Committee discussed whether or not it should further define “be notified immediately.” It agreed that immediate notification should be made no more than 7 days after a member transplant center is notified or becomes aware of a change in staff. This interpretation parallels similar CMS regulations for notification.

It was agreed that the transplant center would have 30 days to submit a complete application form before a change took place. Appendix A of the Bylaws presently defines the application process and the components of a complete application. If the application is not received by the specified due date one of the following actions may be taken:

- The MPSC can make a recommendation to the Board of Directors that the Board notify the Secretary, and/or
- It can take appropriate action in accordance with Appendix A of the Bylaws, including actions defined as adverse under Section 3.01A.
- Alternatively, if there are no doctors at the center who meet the requirements to serve as the primary transplant surgeon and physician, the center should immediately inactivate the affected program(s). Failure to take action by taking one of these steps will result in a recommendation to the Board as noted above.

The work group also proposed language that would address a change in the designation of the key person when the current primary has not left and remains actively involved with the program, i.e., they are still listed as an “additional” surgeon/physician.

All agreed that if a program has staff on site who would meet the requirements for primary surgeon and physician, it may not be necessary for the program to inactivate while UNOS processes the application.

The Committee agreed that the requirements for reporting changes in primary lab directors, OPO Executive Directors and OPO Medical Directors should be reviewed by the specialists on the Committee and similar proposals developed.

Alternatives considered:

The Committee considered other alternatives for ensuring patient safety in a program that cannot demonstrate that it has qualified individuals actively participating in the programs. For example, it discussed the option of allowing programs to initially submit an interim transition plan if it cannot meet the 30 day timeline for submitting an application. It agreed that OPTN/UNOS does not allow a program

to start without a qualified primary surgeon and primary physician so it did not seem reasonable to allow a program to continue to run without both of these individuals.

The Committee also reviewed the other mechanisms that might be used for learning about changes in key personnel such as

- Address change notices.
- Individual submitted as member of team in an application for another center.
- Announcements in periodicals
- Returned mail and email bounce back messages
- Annual staffing audit that is sent to each member transplant center.
- Changes in UNet account access (i.e. record made inactive)

While all of the above methods might be helpful in discovering otherwise unreported changes in key personnel, none of them alone or in combination are sufficient as a primary means of notification to OPTN/UNOS. Only the Annual Staffing Audit is a formal method for monitoring member compliance. Since it is not formally required in the bylaws, however, adverse actions cannot be taken against members who fail to return the Staffing Audit.

The Committee also discussed placing the burden of notification on the individual rather than or in addition to the center, but agreed that the member institution is the responsible party. That decision does not preclude the individual from providing notice but rather places the burden of compliance on the member institution.

Strengths and weaknesses:

The Committee agreed that there is a problem with members complying with the current requirements for providing notice and submitting complete applications even though both of these issues are addressed to some extent in the Bylaws.

In June 2006, the Committee began sending second notice letters to those centers that fail to submit Key Personnel Change Applications within 15 days after the primary transplant surgeon or physician has left the program. The Committee requests that within 14 days of receiving that second notice letter, the center must send UNOS an application or a letter voluntarily inactivating or withdrawing the program's designated status. The center is also notified that, if it does not respond, the Committee will recommend that the Board of Directors declare the member a "Member Not in Good Standing." This protocol is usually effective in obtaining the application or compelling the member to make decision about inactivating or withdrawing the program, but is only effective if the OPTN/UNOS has been notified about the change in the first place.

Problems observed under the current bylaws:

- An application for a change in primary transplant surgeon/ physician is rarely received a full 30 days in advance of a departure.
- Succession plans are not in place in many programs and this often leads to delays in submitting the required documentation.
- The Bylaws do not differentiate between departures and situations where the current primary surgeon or physician assumes a new role within the program.

- Appendix A of the Bylaws already addresses member compliance and the recommendations the Committee can make when centers fail to abide by the requirements. Members do not seem to take the requirements for submitting complete and timely applications seriously, however, and the MPSC has not placed an emphasis on strictly enforcing the bylaws until now.

Strengths of proposed changes to the bylaws:

The proposed changes to the bylaws provide definitions for the types of key personnel changes that the transplant centers are required to report. It also clarifies the following:

- Time period for notification.
- Application is expected to be complete when submitted or completed within 30-days.
- The actions a center must take if it cannot submit a completed application by the deadline.
- What will happen to centers that fail to provide notice or submit a completed application?

The proposal attempts to address the most common situations. It is not possible to implement a proposal that addresses every possible exception. Limitations in the proposal include:

- An application may be dependent upon information provided by a third party. For example, a late or incomplete application may be caused by a delay in obtaining a letter of reference from someone outside the center.
- Unanticipated incidents and exceptions for providing notice after the fact (in the case of illness, death, or military service, for example) are not accommodated in bylaw. The Committee agreed that it would address enforcement individually in these cases.

Description of intended and unintended consequences

Intended Consequences:

- Programs will be more aware of the requirements for submitting a notice to the OPTN/UNOS when there is a change in primary surgeon or primary physician.
- Programs that are unable to demonstrate that they meet the requirements will understand the expectation that they voluntarily inactivate or withdraw the program while they resolve staffing issues.
- Patient safety can be better assured if programs continuously meet minimum staffing requirements.
- Programs will be more cognizant of the need to do succession planning so that they will have smooth transitions when there are changes in key personnel.
- Application turnaround time from submission to approval will improve because of fixed deadlines for submitting completed applications as well as more definite consequences for not meeting these deadlines.
- UNOS staff will spend less time working with centers that fail to submit complete applications and can therefore process application approvals more efficiently.

Unintended Consequences:

- Programs will expect staff and/or the Committee to complete reviews within 30-days of receipt and inform them if the application is incomplete. If a large number of applications arrive at the same time, staff may not be able to respond to the member that quickly. The burden will remain with the center to assure that the application is completed regardless of its processing status.

Burden on Programs:

- Programs will need to be aware of the notification requirements and have procedures which make certain that they are followed.
- Programs will need to develop procedures and designate staff that will ensure that applications are complete when submitted.

Ideas not addressed in the proposal:

- Could UNOS develop a website where physicians could deposit their logs, letters of recommendation, etc. in a personal portfolio?

Supporting Evidence and/or Modeling:

Information tracked in the membership database can be used to demonstrate how often members are not compliant with the notification standard; and how often incomplete applications are submitted, and the length of time it takes for them to be completed.

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

The OPTN has certain responsibilities that are specified by NOTA and the Final Rule. They include establishing experience and training criteria for key surgical and medical transplant personnel and protecting the public health and safety in the context of transplantation.

Statutes pertaining to the OPTN which pertain to this proposal are found in *Title 42, United States Code (USC), Public Health, PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.*

§ 121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4;

[Sections iv – vii and Section 3 omitted]

§ 121.4 OPTN policies: Secretarial review and appeals.

(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

(1) Policies for the equitable allocation of cadaveric organs in accordance with §121.8;

(2) Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;

(3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:

(i) Ensuring that payment of the registration fee is not a barrier to listing for patients who are unable to pay the fee;

(ii) Procedures for transplant hospitals to make reasonable efforts to obtain from all available sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

(iii) Recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and

(iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;

(4) Policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by §121.9;

[Sections 5-6 omitted.]

HHS Program Goals	Strategic Plan Goals
Increase number of deceased donor transplants	Increase donors and transplants in support of HHS Program Goals
Increase life years gained	Optimize a safe environment for living donor transplantation
Increase organs transplanted/donor – non-DCD	Improve compliance with policies to protect patient safety and preserve public trust
Increase organs transplanted/donor – DCD	Improve the OPTN data system

Plan for Evaluating the Proposal:

- **What questions or hypotheses are guiding the evaluation of the proposal?** Answers to these questions should help determine whether or not the proposal is meeting its intended goal(s).
 - Are members submitting notices within required time?
 - Are applications complete at the time of initial submission?
 - How often are members submitting incomplete applications and utilizing the permitted 30-days to complete it?
 - How often did the MPSC take action against a center that was non-compliant with either the notification period or the submission of complete applications?

- How frequently are centers inactivating or withdrawing programs when they are unable to meet the requirements?

Policy Performance Measures:

Data which is stored in the Membership Database will continue to be used to evaluate member compliance and the timeline for application processing.

Time Line for Evaluation:

For the first year after implementation the Committee will evaluate the impact of these proposed changes during each of its scheduled meetings (three times yearly).

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Transplant Centers, OPO’s, and histocompatibility Laboratories are responsible for notifying UNOS at least 30 days before a change in key personnel occurs.

This proposal will not require programming in UNetSM but additional fields may be required in the Membership Database in order to more effectively track compliance with the requirements, produce reports for monitoring, etc.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Primary transplant surgeons, primary transplant physicians, transplant program directors, transplant administrators, OPO Directors, OPO Medical Directors, Lab Directors.	Electronic (email sent from the UNOS Communications mailbox)	30 days after the board approves the change.
UNOS Update (short article in the policy section)	Same as above		Issue following approval by the Board
Regional Meetings	Same as above		Next meeting after approval by the Board

Education/Training Activities			
Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
OPTN Evaluation Plan [This document explains to OPTN Member transplant centers, OPOs and histocompatibility labs how UNOS, as the OPTN contractor, assesses compliance by those members with OPTN Policies and By-laws. The Plan also includes specific expectations as to how Members remain in compliance.]	OPOs, Transplant Centers, Histocompatibility Laboratories	Posted on OPTN website and notice of updated document sent via email	Distributed quarterly

Monitoring and Evaluation:

Membership department staff will evaluate how well centers comply with this bylaw. We will examine data that shows how often members are not compliant with the notification standard; and how often they submit incomplete applications, and how long it takes them to complete the applications.

Enhancements to and reports from the Membership Database will enable more accurate tracking of member compliance.

Bylaw Proposal:

**APPENDIX B TO BYLAWS
OPTN**

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. No Changes

II. Transplant Hospitals.

A. – D. No Changes

- E. Key Personnel.** The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

~~When the Transplant Hospital learns that one or more of these individuals plan to leave, the OPTN Contractor must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to the OPTN Contractor the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~Failure to inform the OPTN Contractor of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.~~

[Note: Above text removed because it is not relevant to new program approval, the primary focus of this section of the bylaws]

**ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS**

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

I. – II. No Changes

- III. Reporting ~~Changes in~~ Key Personnel Changes:** Designated transplant programs must have key personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below.

When a designated transplant program learns that a key person (such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's OPTN approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence), the OPTN Contractor must be notified immediately as described below. The member must also follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A.

Reporting Key Personnel Changes:

- (1) Key Personnel Changes where the primary transplant surgeon and/or primary transplant physician is no longer involved with the program:

When the Transplant Hospital learns that one or more of these individuals plan to leave, or otherwise cease their active participation in the transplant program, the OPTN Contractor must be notified immediately in writing.

At least 30 days (if possible) prior to the end of the individual's active participation in the program, departure of the key person, the Transplant Center shall submit to the OPTN Contractor the name of the replacement key person, Curriculum Vitae, a complete Personnel Change Application, which and information demonstrating and documenting compliance with OPTN criteria for a designated transplant program, whether that the proposed new primary transplant surgeon or physician individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

Programs that are unable to demonstrate that they have on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician should voluntarily inactivate their membership, or relinquish or terminate Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

- (2) Key Personnel Changes, where the primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon/physician:

When the transplant hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, the OPTN Contractor must be notified immediately in writing. At least 30 days prior to the change in the individual's status, the Transplant Hospital shall submit a complete Personnel Change Application to the OPTN Contractor, which documents that the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

Failure to inform the OPTN Contractor of any changes in key personnel may in primary transplant surgeon and/or primary transplant physician shall result in disciplinary action— a recommendation to the Board of Directors that the Board 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.

Processing Applications: For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.

APPENDIX B TO BYLAWS, UNITED NETWORK FOR ORGAN SHARING
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

APPENDIX B TO BYLAWS

UNITED NETWORK FOR ORGAN SHARING

II. Transplant Hospitals.

A-D No changes

- E. Key Personnel.** The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

~~When the Transplant Hospital learns that one or more of these individuals plan to leave, UNOS must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to UNOS the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~Failure to inform UNOS of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.~~

ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS
Designated Transplant Program Criteria

I.-II. No Changes

- III. Reporting ~~Changes in~~ Key Personnel Changes.** Designated transplant programs must have key personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below.

When a designated transplant program learns that a key person (such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence). UNOS must be notified immediately as described below. The member must also follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A.

Reporting Key Personnel Changes:

- (1) Key Personnel Changes where the primary transplant surgeon and/or primary transplant physician is no longer involved with the program:

When the Transplant Hospital learns that one or more of these individuals plans to leave, or otherwise cease their active participation in the transplant program, UNOS must be notified immediately in writing.

At least 30 days (if possible) prior to the end of the individual's active participation in the program departure of the key person, the program Transplant Center shall submit to UNOS the name of the replacement key person, Curriculum Vitae, a complete Key Personnel Change Application, which and information demonstrating and documentsing compliance with UNOS criteria for a designated transplant program that the proposed new primary surgeon or physician meets the requirements specified in this Appendix B, Attachment I and applicable subsections.

Programs that are unable to demonstrate that they have on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician should voluntarily inactivate their membership, or relinquish or terminate Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

- (2) Key Personnel Changes, where the primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon/physician:

When the transplant hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, UNOS must be notified immediately in writing. At least 30 days prior to the change in the individual's status, the Transplant Hospital shall submit a complete Personnel Change Application to UNOS, which documents that the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

Failure to inform the OPTN Contractor of any changes in key personnel may in primary transplant surgeon and/or primary transplant physician shall result in disciplinary action- a recommendation to the Board of Directors that the Board 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.

Processing Applications: For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.