

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)  
Report to the Board of Directors  
November 12-13, 2014  
St. Louis, MO**

**Jonathan M. Chen, MD, Chair  
Debra L. Sudan, MD, Vice Chair**

**Contents**

<b>Action Items .....</b>	<b>2</b>
1. Membership Status Changes and Application Issues .....	2
2. Data Submission and Accuracy in Reporting .....	2
3. Requests for Exceptions Based on Geographic Isolation .....	3
<b>Committee Projects .....</b>	<b>3</b>
4. Pre-Transplant Performance Review (CPM) .....	3
5. Quality Assessment and Process Improvement Requirement (QAPI) .....	4
6. Transplant Hospital Definition Project .....	4
7. Joint Society Working Group Projects .....	5
<b>Committee Projects Pending Implementation .....</b>	<b>5</b>
8. Proposal to Revise the Current Method for Flagging Transplant Programs Post-transplant Performance Review .....	5
<b>Implemented Committee Projects .....</b>	<b>6</b>
<b>Review of Public Comment Proposals .....</b>	<b>6</b>
<b>Other Committee Work .....</b>	<b>6</b>
9. Site Survey Innovation .....	6
10. Member and Applicant Related Report of Committee Actions .....	6
11. Live Donor Adverse Events Reporting .....	6
12. OPO Metrics .....	7
13. Due Process Proceedings and Informal Discussions .....	7
14. Approval of Committee Actions .....	7
<b>Meeting Summaries .....</b>	<b>7</b>

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*This report reflects the work of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) Committee between June 2014 and October 2014.*

**Action Items**

**1. Membership Status Changes and Application Issues**

The Committee is charged with determining that member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee reviewed the applications and status changes listed below and will make recommendations to the Board to take the following actions:

New Members

- Fully approve 2 new transplant hospitals
- Fully approve 4 medical/scientific, public organizations, individual, and business members for two year terms

Existing Members

- Fully approve 5 transplant programs and 2 living donor components
- Fully approve 16 Vascularized Composite Allograft (VCA) programs
- Conditionally approve 1 transplant program for 24 months
- Conditionally approve 1 transplant program for 12 months
- Approve 4 transplant program reactivations
- Approve 1 conditional living donor component reactivation for 12 months
- Approve 1 living donor component for full approval that previously had 12 month conditional approval

**2. Data Submission and Accuracy in Reporting**

*Public Comment:*     [March 14 – June 13, 2014](#)

The Committee previously distributed a proposal for Public Comment in March 2014 that modifies Policy 18 to state explicitly that members must submit accurate data and that members are responsible for providing documentation to verify the accuracy of their data. The Committee reviewed and discussed public comment feedback on its September 4, 2014, conference call. During its discussion, the Committee decided to add the words “upon request” to the proposed language, to make it clearer that the members are not responsible to continually maintain and submit any additional

documentation during routine audits, but are instead required to be able to access documentation and provide it at the request of the MPSC.

**RESOLVED, that the additions and modifications to Policy 18.1 (Data Submission Requirements) as set forth in Exhibit A, are hereby approved effective February 1, 2015.**

### **3. Requests for Exceptions Based on Geographic Isolation**

*Public Comment:* [March 14 – June 13, 2014](#)

The Board is asked to approve language that establishes a mechanism by which the MPSC can make a recommendation to the Board of Directors that the Board consider designating and approving a transplant program that cannot meet key personnel qualifying criteria because the applicant is located in a geographically isolated area, specifically Hawaii, Puerto Rico, and Alaska. The Committee voted 26 For, 0 Against, and 0 Abstentions to recommend the Board of Directors approve the following new bylaw:

**RESOLVED, that Bylaw Section A.3.F. (Geographically Isolated Transplant Program Applicants) as set forth in Exhibit B, is hereby created, effective February 1, 2015.**

## **Committee Projects**

### **4. Pre-Transplant Performance Review (CPM)**

*Public Comment:* [September 29 – December 5, 2014](#)

*Board Consideration:* June 2015 (Estimated)

Currently, transplant program performance monitoring relies almost exclusively on risk-adjusted graft and patient survival rates among recipients. The overemphasis on post-transplant metrics may result in risk-aversion and decreased transplant volumes, and may not be in the best interest of waitlisted patients. Further, post-transplant outcomes may not identify structural problems (e.g., understaffing) that prevent a program from keeping up with the needs of its waitlist population. As such, a more holistic approach to performance monitoring is necessary.

A Committee work group has spent a number of years working with the SRTR and UNOS staff to develop a metric for review of pre-transplant performance. This work has resulted in a tool, the Composite Pre-transplant Metric (CPM), for identifying kidney and liver programs that may be in need of review based on outlying performance in accepting deceased donor organ offers, transplanting waitlisted patients, and/or mitigating waitlist mortality. The CPM is an aggregate, pre-transplant performance metric that combines programs' acceptance rate, geography-adjusted transplant rate, and waitlist mortality rate observed-to-expected (O/E) ratios into a single number for prioritizing programs for potential review. At its December 2013 meeting, the Committee agreed that the CPM was ready for public comment and requested that proposed Bylaw language be presented to the Committee at its March 2014 meeting.

Prior to the March meeting, the SRTR informed UNOS staff that it was considering making changes to the acceptance rates models utilized by the composite pre-transplant metric (CPM) analysis. The CPM work group met on June 9, 2014 to review a data analysis of the effect of the changes and concluded that these changes did not

significantly affect the CPM results and recommended that the Committee move forward to public comment. The work group recommended the use of CPM and two safety net metrics to identify programs for review.

On the June conference call, the Committee approved proposed bylaw language to establish review of pre-transplant performance for transplant programs. Following discussion, the Committee removed the safety net metric based on transplant rate from the language. The proposal was distributed for fall 2014 public comment.

## **5. Quality Assessment and Process Improvement Requirement (QAPI)**

*Public Comment:* [September 29 – December 5, 2014](#)

*Board Consideration:* June 2015 (Estimated)

During its reviews, the Committee has observed that members who are having difficulty with compliance or performance often do not have well developed quality assurance performance improvement (QAPI) programs. The Committee concluded that there appears to be a correlation between underperformance in the areas of compliance and outcomes and the lack of a robust QAPI program. Currently, the OPTN bylaws and policies do not contain a requirement for a QAPI program. As a result, the Committee does not have a basis for taking action when there is a finding that a member's QAPI program is inadequate. The Committee requested that an OPTN QAPI requirement be developed. During its October 2013 conference call and the December meeting, the Committee reviewed CMS requirements and worked on language for an OPTN requirement.

The Committee approved proposed Bylaw language at its March 2014 meeting. On the June conference call, the Committee discussed the appropriate monitoring plan for the proposed bylaw to require transplant programs and OPOs to establish QAPI plans and implement those plans. Through a consensus, the Committee decided that monitoring of QAPI would occur in conjunction with an existing compliance or performance matter.

This proposal was submitted to the Policy Oversight Committee (POC) and Executive Committee for their review prior to public comment. The POC recommended that this proposal not be released for public comment due to concerns with overlapping CMS requirements. (10 against and 4 wanting it to proceed to public comment.) After discussion, the Executive Committee agreed to distribute the proposal for public comment in fall 2014.

## **6. Transplant Hospital Definition Project**

*Public Comment:* [September 29– December 5, 2014](#)

*Board Consideration:* June 2015 (Estimated)

The proposed changes to the transplant hospital definition are needed to better describe attributes requiring consideration by the Committee when it is assessing applications for OPTN/UNOS membership and transplant program designation. A transplant hospital member is currently defined by the Bylaws as “a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ” and by Policy as “a health care facility in which transplants of organs are performed”. A lack of distinguishing detail in the transplant hospital definition has proven to be problematic when assessing membership healthcare institutional configurations consisting of multiple “hospitals” performing the same organ transplants at geographically separated sites.

The goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance concerning patient safety, patient outcomes, and overall compliance with approved OPTN/UNOS directives.

During its June teleconference, the Committee received an update on the working group's efforts to improve the definitions of a transplant hospital member that are found in OPTN Policy and Bylaws. The Committee then considered, and unanimously approved (21 For, 0 Against, and 0 Abstentions), final language to be proposed during the fall 2014 public comment cycle.

## **7. Joint Society Working Group Projects**

*Public Comment: August 2015 (Estimated)*

*Board Consideration: December 2015 (Estimated)*

The Joint Society Policy Steering Group opted earlier this year to form a Joint Society Working Group (JSWG) to address a number of MPSC projects, and one Pancreas Committee project, that pertain to key personnel requirements in the Bylaws. Specifically, the JSWG has been charged with developing recommendations for the following topics:

- foreign board certification,
- approved transplant fellowship training programs,
- multi-organ procurement requirement for primary surgeons,
- procurement requirement for primary surgeons,
- procurement observation requirement for primary physicians,
- consider primary/first assistant requirement for primary surgeons,
- define "working knowledge" in primary physician pathways,
- primary physician specialty and subspecialty board certifications,
- currency requirements for key personnel, and a
- review of the pancreas key personnel Bylaws (originated from Pancreas Committee).

The JSWG is in the midst of discussing these topics during regularly scheduled teleconferences. The MPSC will receive an update on the group's initial progress at its December 2014 meeting. Due to the overlapping language and intertwined nature of some of these topics, the JSWG feels it is necessary to perform a final assessment of all its recommendations together before they are formally presented. Considering this, it is anticipated that modifications to the Bylaws to address these topics will be proposed during the public comment cycle that begins in August 2015.

## **Committee Projects Pending Implementation**

### **8. Proposal to Revise the Current Method for Flagging Transplant Programs Post-transplant Performance Review**

*Public Comment: [September 6 – December 6, 2013](#)*

*Board Approval: [June 2014](#)*

*Implementation: [January 1, 2015](#)*

## OPTN/UNOS Membership and Professional Standards Committee

At the June 2014 meeting, the Board of Directors approved revisions to the current method for identifying transplant programs for post-transplant performance reviews. The resolution included a January 1, 2015 effective date. The new Bayesian methodology and thresholds will be used in the reports provided by the SRTR to programs on their secure sites in December 2014. The MPSC will review these reports at its spring 2015 meeting after the January 1, 2015 effective date.

### **Implemented Committee Projects**

None

### **Review of Public Comment Proposals**

None

### **Other Committee Work**

#### **9. Site Survey Innovation**

The Committee was updated on the Site Survey Innovation Project. The project, which was developed in the department of evaluation and quality, is a multi-phase, long-term initiative to re-envision and improve the entire site survey process. The goals of the project are to improve consistency, make the survey more relevant to members, and to provide more relevant data to the MPSC. The department has already taken steps to improve internal processes. Input on next steps and potential improvements will be sought from the MPSC and other stakeholders as the review moves forward. A MPSC work group will be established to work through the details.

#### **10. Member and Applicant Related Report of Committee Actions**

The Committee reviewed and approved the following:

- 60 Applications for changes in transplant program personnel
- 3 applications for a change in primary laboratory director.

The Committee also received notice of the following membership changes:

- 4 programs and 3 living donor components inactivated
- 2 programs, 1 living donor component, and 1 laboratory withdrew from membership
- 2 OPO Key Personnel Changes

The Committee discussed an application from a transplant hospital member that had not met the key personnel change notification requirements in the Bylaws and issued a Notice of Uncontested Violation.

#### **11. Live Donor Adverse Events Reporting**

As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data) and Policy 12.8.5 (Reporting of Non-utilized Living Donor Organs), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. Transplant programs also must report instances when a recovered live donor organ is transplanted into a recipient other than the intended recipient within 72 hours. The Committee reviewed three mandatory reported cases: one living donor death, one redirected living donor organ and one non-utilized organ. The Committee was also informed of a voluntary report of a living donor

death after two years and unrelated to donation. The Committee issued one Letter of Warning, and closed the other two issues with no action. The Committee is not recommending any further action to the Board at this time for any of the issues.

## **12. OPO Metrics**

At the July meeting, the Committee reviewed eight organ procurement organizations (OPOs) for lower than expected organ yields. Following its review, the Committee recommended that three OPOs newly identified in the Spring 2014 cohort be sent an initial inquiry and five OPOs that had previously entered review continue in monitoring by the Committee. The Committee also considered recommendation from the OPO Metrics Focus Group and approved the following recommendations:

- Suspend use of initial survey until the focus group can revise the survey
- Postpone reconsideration of the review of OPO pancreas yields until one year after implementation of the pancreas allocation system.

## **13. Due Process Proceedings and Informal Discussions**

During the July meeting, the Committee conducted four interviews and one informal discussion with member transplant hospitals. The interviews and informal discussion were convened as provided for in Appendix L (Reviews, Actions, and Due Process) of the Bylaws.

## **14. Approval of Committee Actions**

During the meetings held on June 17, July 9-10, and September 4, the Committee unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

## **Meeting Summaries**

The Committee held meetings on the following dates:

- June 17, 2014
- July 8-10, 2014
- September 4, 2014
- September 15, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=8>.

***Proposal to Clarify Data Submission and Documentation Requirements***

**Table of Contents**

**Proposal to Clarify Data Submission and Documentation Requirements ..... 1**

Summary and Goals of the Proposal: .....2

Background and Significance of the Proposal: .....2

Supporting Evidence and/or Modeling: .....3

Expected Impact on Living Donors or Living Donation: .....3

Expected Impact on Specific Patient Populations:.....3

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule: .....3

Plan for Evaluating the Proposal:.....3

Additional Data Collection: .....3

Expected Implementation Plan: .....3

Communication and Education Plan: .....4

Compliance Monitoring: .....4

Policy Proposal: .....5

Public Comment Responses.....6

    1. Public Comment Distribution .....6

    2. Primary Public Comment Concerns/Questions .....6

    3. Regional Public Comment Responses.....6

    4. Committee Public Comment Responses .....7

    5. Individual Public Comment Responses.....8

Post Public Comment Consideration: ..... 11

***Proposal to Clarify Data Submission and Documentation Requirements***

**Sponsoring Committee:** Membership and Professional Standards Committee (MPSC)

**Summary and Goals of the Proposal:**

OPTN Policy 18.1 (Data Submission Requirements) requires members to submit data to the OPTN through the use of standardized forms. However, Policy 18.1 does not explicitly state that the data submitted must be accurate or that members must be able to provide documentation to verify the accuracy of their data submissions. The MPSC historically has agreed that the need for accurate data is implied within Policy 18.1, as is the member's obligation to provide documentation to verify the data's accuracy, if requested. This proposal's goal is to amend Policy 18.1 to state explicitly that data must be accurate and that members must provide documentation to support their data submissions.

**Background and Significance of the Proposal:**

The MPSC reviews reports of inaccurate and falsified data submissions as part of its role to monitor member compliance and patient safety. The MPSC cites members for noncompliance with Policy 18.1 when members submit inaccurate data. Some members who have been cited have responded that they do not understand the citation; they believed that they were complying with the policy when they submitted the information, and they noted that the policy does not state the data must be accurate. Staff have to explain to these members that the need for accurate data is implied within the policy. In addition, staff often have to make multiple requests for documentation before members submit information.

The MPSC has asked members to submit documentation to verify the data's accuracy; however, Policy 18.1 does not explicitly state that members must provide such documentation. Prior to the 2013 plain language rewrite of the policies, there were some policies that stated members were required to maintain documentation within patient records or to submit source documentation for auditing. Some members suggested that because some policies include specific obligations to maintain or provide data, and because Policy 18.1 does not similarly specify the need to provide documentation, no such obligation exists.

The MPSC recognized the need to clarify policy language after reviewing a number of data accuracy cases and receiving the feedback from members, as mentioned above. By explicitly stating member obligations within Policy 18.1, the proposal aims to eliminate member confusion.

The MPSC historically has agreed that all data reported to the OPTN should be appropriately documented and considered proposing a new bylaw that would require members to provide documentation for all data rather than the policy change proposed in this document. However, Policy 18.1 has applied to each of the data accuracy cases reviewed by the MPSC, and the current problem is that Policy 18.1 does not explicitly state that members are obligated to provide documentation to support the accuracy of data submitted to the OPTN. Therefore, the MPSC felt that this policy change was a more appropriate action.

The MPSC recognizes that the proposal may be seen as a new requirement to collect and maintain documentation; however, the vast majority of information should already be contained within medical records and documented according to standard medical practice. The MPSC also

recognizes that the necessary documentation for each of the many data elements may be located in different systems or records at OPOs, labs, and hospitals. Therefore, the proposal does not state that members must maintain documentation in a central location for review at any time. Instead, members must be able to obtain and provide documentation to verify data elements upon request by the MPSC.

The MPSC voted on December 11, 2013, to distribute the following proposed modifications to Policy 18.1 for public comment, by a vote of 32 For, 0 Against, 0 Abstentions.

**Supporting Evidence and/or Modeling:**

Not applicable

**Expected Impact on Living Donors or Living Donation:**

While this proposal is not specific to living donors, it would equally apply to data submitted by living donor programs.

**Expected Impact on Specific Patient Populations:**

This proposal would equally impact all patient populations.

**Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:**

The proposal promotes the OPTN's Strategic Plan by promoting the efficient management of the OPTN. In particular, the proposal aims to clearly communicate with members and improve the readability of OPTN rules and requirements. The proposal clarifies member obligations under Policy 18.1. It will also reduce the amount of OPTN resources required to determine whether allegations of inaccurate or falsified data submission are valid by placing the obligation on the member to verify the data's accuracy.

**Plan for Evaluating the Proposal:**

The MPSC will evaluate whether the proposed policy is meeting its goals each time it reviews potential data submission policy violations or receives member feedback regarding violations of Policy 18.1.

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

The proposed change will not require members to alter their policies or procedures. Members should already be submitting accurate data to the OPTN and should be maintaining or have access to all relevant documentation according to standard medical practices. The proposal is meant only to state explicitly that the data submissions must be accurate and that the member is obligated to provide documentation to verify its data accuracy as needed. This proposal will not require programming in UNet<sup>SM</sup>.

**Communication and Education Plan:**

A policy notice will be distributed to members one-month after the Board meeting.

**Compliance Monitoring:**

The proposal is not intended to add any new requirements or to change how members are monitored for compliance with Policy 18.1. UNOS currently monitors members' data accuracy under Policy 18.1 as a part of the routine survey process. Members are required to provide certain documentation to UNOS site surveyors during reviews, and members will continue to be required to provide the same documentation. UNOS site surveyors will not routinely review whether members have additional documentation to verify the accuracy of data submissions; however, if the OPTN is investigating reports of inaccurate or falsified data submissions, a member may be required to submit additional information.

The proposal does not specify what kind of documentation members, if asked, will be required to submit. The member will be asked to submit appropriate documentation to verify the accuracy of the data in question, including source and/or supporting documentation that includes but is not limited to medical record information, lab results, clinic notes, social work notes, etc.

**Policy Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 At a meeting of the OPTN/UNOS Board of Directors convened on November 12-13, 2014, in St.  
2 Louis, Missouri, the following resolution is offered.

3  
4 *A resolution to clarify data submission and documentation requirements.*

5  
6 Sponsoring Committee: Membership and Professional Standards Committee

7  
8 **RESOLVED, that Policy 18.1 is modified as set forth below, effective February 1, 2015.**

9  
10 **18.1 Data Submission Requirements**

11 OPOs must provide donor information required for organ placement to the OPTN Contractor in  
12 an electronic data format as defined and required by the computer system. Deceased donor  
13 information required for organ placement must be submitted prior to organ allocation.

14  
15 Members must report accurate data to the OPTN using standardized forms. *Table 18-1* shows the  
16 member responsible for submitting each data form and when the Member must submit the  
17 following materials to the OPTN Contractor. Members are responsible for providing  
18 documentation upon request to verify the accuracy of all data that is submitted to the OPTN  
19 through the use of standardized forms.

20 #

**Public Comment Responses**

**1. Public Comment Distribution**

Date of distribution: March 14, 2014

Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	24	19 (79%)	0	5 (21%)	1
Regional	11	11 (100%)	0	0	0
Committee	4	3 (75%)	0	1 (25%)	15

**2. Primary Public Comment Concerns/Questions**

The proposal intentionally does not require that members maintain all documentation in a central location or that the documentation is available for auditing at any time. Instead, the proposal requires that members be able to access and provide relevant documentation to support the data's accuracy as needed. As with any OPTN investigation, members are allowed time to collect information and submit a response to the OPTN.

The proposal does not require that members submit primary source documentation for every data element, nor does it prescribe the type of supporting documentation that members must submit. Members are required to submit whatever supporting documentation is available. While certain elements may have primary source documentation, others may only have physician notes or documentation of conversations with the patient.

Lastly, the proposal does not add any new member obligations. The OPTN has always required that members submit accurate data and has asked members to submit documentation to support their data submissions. This proposal's goal is to clarify members' existing obligations in the policy language to avoid any future confusion.

**3. Regional Public Comment Responses**

\*\*Non-Discussion agenda item at regional meetings: proposal not presented or discussed

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	13 yes, 0 no, 0 abstentions		In person
2	3/28/2014	27 yes, 0 no, 0 abstentions		In person
3	5/30/2014	16 yes, 0 no, 0 abstentions		In person
4	5/9/2014	25 yes, 0 no, 0 abstentions		In person
5	6/12/2014	12 yes, 2 no, 3 abstentions		In person
6	5/16/2014	50 yes, 0 no, 0 abstentions		In person
7	5/9/2014	18 yes, 0 no, 0 abstentions		In person

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
8	4/4/2014	15 yes, 0 no, 0 abstentions		In person
9	5/21/2014	15 yes, 0 no, 0 abstentions		In person
10	5/15/2014	18 yes, 0 no, 0 abstentions		In person
11	5/30/2014	24 yes, 0 no, 0 abstentions		In person

#### 4. Committee Public Comment Responses

##### **Living Donor Committee:**

The Committee considered and supported this proposal.

##### **Committee Response:**

The MPSC appreciates the support of the Living Donor Committee.

##### **Operations and Safety Committee:**

The committee considered this proposal during its June 10, 2014, meeting and voted in support as written (9 support, 0 oppose, 1 abstain).

##### **Committee Response:**

The MPSC appreciates the support of the Operations and Safety Committee.

##### **OPO Committee:**

The Committee briefly discussed this proposal following a presentation by one of the liaisons for the Membership and Professional Standards Committee (MPSC). One Committee member asked if members were going to be retroactively reviewed for accurate data submission. MPSC staff noted that the practice has always been to monitor accurate data submission and this proposal will clarify that expectation. The OPO Committee fully supported this proposal due to the importance of accurate data submission.

##### **Committee Response:**

The MPSC appreciates the support of the OPO Committee.

##### **Transplant Coordinators Committee:**

This proposal was presented to the Committee and after some discussion, the Committee opposed the proposal due to the added burden it will have on centers and suggested the policy specifically state which source documents would meet the requirements and for which fields they would be required. (Support 0, Oppose 9, Abstain 4)

##### **Committee Response:**

The proposal does not require that members obtain any additional documentation or that members maintain all documentation in a central location for auditing. The proposal only requires that members document data according to standard medical practices and that they obtain the documentation from the appropriate sources and make it available for review if needed. The MPSC approved a post public comment change to the language that clarifies members must provide documentation upon request by the MPSC and not during routine audits.

The proposal does not specifically state what documentation is required for each data element

because the Committee recognizes that appropriate supporting documentation may vary between members and based on the data in question. For example, members may verify data through a doctor's note in the medical record, radiology imaging, pathology, etc. The Committee also recognizes that some data elements may include medical judgment and/or discretion. The member is responsible for producing whatever documentation applies to the data in question, including any documentation used or referenced as a part of any medical decisions.

## 5. Individual Public Comment Responses

### **Comment 1:**

*Vote: Oppose*

*Date Posted: 03/21/2014*

COMMENT: I'm in support of transplant centers submitting accurate data, however I think the current policy already gives the OPTN sufficient latitude to respond to any center not providing accurate, or verifiable detail.

### **Committee Response:**

The Committee agrees that current policy gives the OPTN latitude to respond to any member that does not provide accurate or verifiable detail. However, based on feedback received from some members, the Committee believes the policy can be modified to more clearly state member obligations and to alleviate any possible confusion in the future.

### **Comment 2:**

*Vote: Oppose*

*Date Posted: 04/22/2014*

COMMENT: I strongly support the idea but this proposal is not broad enough. In addition to standardized forms, members also have to report accurate data prior to allocation (DonorNet<sup>SM</sup> and Waiting List).

### **Committee Response:**

The Committee agrees that all data reported to the OPTN must be accurate and supported with appropriate medical documentation. The Committee intentionally limited the proposal to Policy 18.1 because the Committee has only received push back regarding the need to provide supporting documentation for data reported through Policy 18.1.

### **Comment 3:**

*Vote: Oppose*

*Date Posted: 04/04/2014*

COMMENT: It is implicit in the regulations that the data should be accurate and complete. Upon surveillance from UNOS for recertification, TIEDI data verification is conducted and documentation supporting the data entered is required. It has always been the intent and has always been implied that the data should be accurate, complete, and supported by documentation.

### **Committee Response:**

The Committee agrees that current policy gives the OPTN latitude to respond to any member

that does not provide accurate or verifiable detail. However, based on feedback received from some members, the Committee believes the policy can be modified to more clearly state member obligations and to alleviate any possible confusion in the future.

**Comment 4: AST**

*Vote: Oppose*

*Date Posted: 06/16/2014*

COMMENT: The AST agrees that the data submitted on the data collection forms should be accurate. While the vast majority of information should already be contained within medical records and documented according to standard medical practice, the process of collecting the data from multiple sources and different systems/specialties and having it ready for a potential audit in the future will represent a challenge and burden to transplant programs. We have two specific questions: 1. Some of the information included on the various forms does not reflect discrete data elements, but interpretation from discussions with the patient or review of records. These items include such things as physical capacity, work status, academic progress, angina, peptic ulcer disease, symptomatic cerebrovascular disease, symptomatic peripheral vascular disease, etc. Will the data accuracy and document verification apply only to discrete elements of data on the forms where there is no room for interpretation or also to items as listed here where there is some judgment/discretion involved? If the latter, how will the "accuracy" be determined? 2. What documentation will programs be required to provide to verify the accuracy of the data submitted? Does it need to be in the transplant hospital's medical records or files or can it be data that are abstracted from outside medical records and entered that the transplant hospital could access if requested to do so? If the latter, what time would a program be allowed to have to provide primary source documentation? The policy needs to be clearer about what primary source documentation the transplant center needs to have and for which data elements on the forms in the case of an audit. The AST is not supportive of this proposal without further clarification.

***Committee Response:***

The Committee understands that collecting data from multiple sources and having it ready for a potential audit would represent a challenge and burden to transplant programs. Therefore, the proposal does not require that members have all documentation from various sources available in a single location ready for audit at any time. The proposal only clarifies what is already required of members: that they work to obtain the necessary documentation from various sources and provide it to the OPTN as needed. The Committee approved a post public comment change to the language to clarify that members must submit supporting documentation upon request by the MPSC, not during routine audits.

In response to the AST's specific questions:

- 1) The need to provide documentation to verify data submissions applies to all data, including items that may include medical judgment or discretion. In such instances, the member is asked to provide any relevant documentation, such as documentation of conversations with the patient or the records that were reviewed, as well as an explanation of the decision making process. The Committee then reviews the documentation to confirm that the decision as explained is supported by the appropriate documentation. The Committee does not review the appropriateness of the medical decision, only that the rationale behind the decision is supported through the documentation.
- 2) Members are expected to provide any documentation they believe supports their data submissions and can include information from the transplant medical record as well as

any appropriate outside source. The time frame members have to access and provide the requested information varies based on the nature of the investigation and the data or documentation in question. Members are generally allowed at least two weeks to provide a response during the initial investigation and are given an additional opportunity to provide information before the Committee reviews the investigation's results.

**Comment 5:**

*Vote: Oppose*

*Date Posted: 6/12/2014*

COMMENT: This proposal places the responsibility on the transplant center - when the essential work of defining the "definition" and "source documentation" for each data element has not been done. Putting this policy into place without having provided the definitions and requirements for source documentation does not accomplish the goal. My center could state the diagnosis is verified by MD note, another could require radiology imaging, another pathology. For other national databases such as STS, ASBMT, etc. - the definition and required source documentation is defined, and that is the standard the center is held to in audit. It makes no sense to require the center to verify and maintain without providing the definition and standard.

**Committee Response:**

The proposal clarifies the existing member obligation to submit accurate data and to provide information to the OPTN when requested; this proposal does not shift the responsibility from the OPTN to the member.

Because the Committee recognizes the difficulties associated with defining a source document, the proposal intentionally does not require that members submit source documentation. Members are only expected to provide supporting documentation based on standard medical documentation practices. The Committee recognizes that such documentation may include physician notes, radiology imaging, pathology report, etc.

**Comment 6: ASTS**

*Vote: Support*

*Date Posted: 06/17/2014*

COMMENT: ASTS supports this proposal designed to ensure accurate data reporting. The proposal supports the intent for accuracy and action if deemed necessary upon review. A key component of this proposal will be educational resources for the transplant center to clarify what is an acceptable source document to verify accuracy and how to monitor and ensure accuracy of the data submitted.

**Committee Response:**

The MPSC appreciates the support from ASTS.

**Comment 7:**

*Vote: Support*

*Date Posted: 06/13/2014*

COMMENT: NATCO supports this proposal as written.

***Committee Response:***

The MPSC appreciates NATCO's support.

**Comment 8:**

*Vote: Support*

*Date Posted: 05/28/2014*

COMMENT: There is a concern regarding what "supporting documentation" will be required

***Committee Response:*** The Committee recognizes that documentation practices may vary slightly between members and does not wish to burden members by specifying that members may only submit certain types of documentation or by requiring that members collect any additional documentation. The Committee accepts any documentation that is considered appropriate based on standard medical documentation practices.

**Post Public Comment Consideration:**

The Committee met via conference call on September 4, 2014, to review public comments received on the proposal. Based on the comments the Committee unanimously decided to amend the proposal and add "upon request" so it is clear members are not required to maintain any additional documentation or to make any additional documentation available for regularly scheduled audits.

***Proposal for Requests for Exceptions Based on Geographic Isolation***

**Table of Contents**

Title: Requests for Exceptions Based on Geographic Isolation .....2

Sponsoring Committee: Membership and Professional Standards Committee (MPSC) .....2

Summary and Goals of the Proposal: .....2

Background and Significance of the Proposal: .....2

Expected Impact on Living Donors or Living Donation: .....3

Expected Impact on Specific Patient Populations:.....3

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule: .....3

Plan for Evaluating the Proposal:.....3

Expected Implementation Plan: .....4

Communication and Education Plan: .....4

Compliance Monitoring: .....4

Bylaw Proposal: .....5

Public Comment Responses.....6

    1. Public Comment Distribution.....6

    2. Primary Public Comment Concerns/Questions .....6

    3. Regional Public Comment Responses.....6

    4. Committee Public Comment Responses.....8

    5. Individual Public Comment Responses .....10

Post Public Comment Consideration: .....11

**Title:** Requests for Exceptions Based on Geographic Isolation

**Sponsoring Committee:** Membership and Professional Standards Committee (MPSC)

**Summary and Goals of the Proposal:**

The proposed Bylaws language establishes a mechanism by which the MPSC can make a recommendation to the Board of Directors that the Board might consider designating and approving a transplant program that currently cannot meet key personnel qualifying criteria because the applicant is located in a prescribed geographically isolated area, specifically Hawaii, Puerto Rico, and Alaska.

Currently, if an applicant cannot meet transplant program qualification criteria, the application is rejected and closed by the MPSC. To pursue this matter further, the applicant is left to appeal to the HHS Secretary for any further transplant program approval consideration. The MPSC believes that there are situations where an applicant may be qualified to perform organ transplantation, but unable to meet transplant program approval requirements due to the hospital being geographically isolated. This proposal was prompted by a situation where the Committee recognized it could not approve a non-qualified applicant so it forwarded a new transplant program application to the Board with declared support for Board consideration and approval. The Board declined to address this applicant with declared support primarily due to having no set process for undertaking such actions.

**Background and Significance of the Proposal:**

In July 2012, the MPSC reviewed an application for a new pancreas transplant program at The Queens Medical Center (HIQM) in Hawaii. The applicant's proposed key personnel previously had effectively performed pancreas transplantation at a now closed Hawaiian transplant hospital. This closed pancreas transplant program was originally approved in 1992 and performed pancreas transplant surgery there under the direction of the new program's proposed primary surgeon until its closure in December 2011. The closed pancreas transplant program never appeared before the MPSC for outcome related issues and never received OPTN sanctions.

The submission of a new pancreas transplant program application requires the MPSC to review it for compliance with current designation and approval requirements. While the proposed primary surgeon met pancreas program training or experience transplant volume requirements in 1992, he did not meet the requirements upon submission of the new pancreas transplant program application. Specifically, his pancreas transplant case numbers are not large enough to meet or maintain primary pancreas surgeon qualifying criteria. A major reason for this is the limited opportunity to perform pancreas transplantation in a geographically isolated area such as Hawaii.

The majority of the pancreas transplant staff from the closed transplant hospital moved to the applicant facility. The transplant hospital applying for pancreas program approval stated that the proposed primary surgeon and physician cannot take time away from their other transplant program duties to obtain the necessary pancreas transplant experience at another transplant program. They believe that success at the closed pancreas transplant program indicates they are qualified. Because essentially the same pancreas transplant team which led the prior pancreas transplant program at the closed transplant hospital would be the foundation of the applicant

program, the MPSC believes it should be able to recommend that the Board consider approving this applicant. No mechanism existed to do this, thus the proposed bylaw.

The proposed Bylaws is intended to address all organ types. “Geographically isolated” is defined in the context and application of this provision. The intent is to remove any ambiguity or misunderstanding regarding what is intended. Exceptions to existing transplant program designation and approval criteria are highly undesirable, so this language is intended to be specific and limiting in scope regarding application approval. The applying program must have demonstrated previous transplant experience and an MPSC and OPTN sanction free record.

This proposal was approved by the MPSC for public comment on December 5, 2012, with a vote of 23 for, 13 against, and 0 abstentions.

**Expected Impact on Living Donors or Living Donation:**

This proposal establishes a process for the Board of Directors to consider the approval of transplant programs in geographically isolated areas that are unable to meet all program approval requirements as outlined in OPTN Bylaws. This process could be used for the Board to consider, and ultimately approve at its discretion, living donor recovery programs at transplant hospitals located in geographically isolated areas.

**Expected Impact on Specific Patient Populations:**

If a transplant hospital is located in geographic isolation and there is a patient population which can benefit from transplantation, but is not being served, the expected impact of approving a safe and successful transplant program is substantial.

Using the Hawaiian pancreas transplant program case as an example, in Hawaii there are approximately 100,000 diabetic patients, of which 40,000 patients are also experiencing kidney disease. All of the recent pancreas transplants were combined with a kidney. Currently, all kidney-pancreas candidates have to leave the islands to receive a transplant. In addition, donor pancreata go unused due to the lack of a local pancreas transplant program.

**Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:**

The following two OPTN Strategic Goals and Priorities support the changes:

- Maximum Capacity – The proposed changes will help to maximize the number of donors and transplants by approving capable transplant program applicants who serve a defined geographically isolated area.
- Increase Access – The designation and approval of capable transplant programs in geographically isolated areas provides an opportunity for the patients to seek transplant treatment for end stage organ disease which might not be available due to their place of residence.

The transplant community recognizes that there are exceptions that may exist to conventional transplant program designation and approval requirements. Transplanting in geographical isolation is one of these situations and the goal of this proposed bylaw is to address any unintended disadvantages to transplant hospitals working in such conditions.

**Plan for Evaluating the Proposal:**

The MPSC will monitor the number of times this situation occurs and evaluate if the allowance leads to any modification in the transplant program application process. This monitoring will also include registering transplant program applicants not considered geographically isolated who request special approval consideration when proposed primaries do not fulfill qualification criteria. This information will be made available to the MPSC each time a special consideration request is made.

**Expected Implementation Plan:**

If approved by the Board of Directors, this option will be immediately available upon the implementation date. An applicant's inability to meet current key personnel requirements is the only program approval criteria which can be used for special consideration. Judgment of key personnel regarding satisfactory level of experience and transplant program success is a transplant peer assessment purposely left undefined in the bylaw. An MPSC recommendation to the Board for consideration of program approval does not convey interim approval and program initiation. Program approval and transplantation can only occur once Board program approval is granted.

**Communication and Education Plan:**

- Policy notice upon Board approval utilizing regular communication channels.
- OPTN Membership Department will directly inform transplant hospitals in Alaska, Hawaii, and Puerto Rico of the new provision in the transplant program approval Bylaws.

**Compliance Monitoring:**

This proposal will not alter monitoring of designated transplant programs approved by the Board of Directors. Any changes to approved primary surgeons and physicians will be handled and reviewed using current Bylaws requirements. Each situation will be handled independent of any prior decisions.

**Bylaw Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 At a meeting of the OPTN/UNOS Board of Directors convened on November 12-13, 2014, in St.  
2 Louis, Missouri, the following resolution is offered.

3  
4 *A resolution to approve language that establishes a mechanism by which the Membership and*  
5 *Professional Standards Committee can make a recommendation to the Board of Directors that it*  
6 *consider designating and approving a transplant program that cannot meet key personnel*  
7 *qualifying criteria because the applicant is located in a geographically isolated area, specifically*  
8 *Hawaii, Puerto Rico, and Alaska.*

9  
10 Sponsoring Committee: Membership and Professional Standards Committee

11  
12 **RESOLVED, that section A.3.F. (Geographically Isolated Transplant Program Applicants)**  
13 **is added to the OPTN Bylaws, as set forth below, effective February 1, 2015.**

14  
15 **A.3.F. Geographically Isolated Transplant Program Applicants**

16 The MPSC may recommend to the Board of Directors the approval of a designated transplant  
17 program if the prospective program cannot satisfy the current key personnel requirements due to  
18 its geographical isolation. Geographically isolated applicants must demonstrate to the MPSC that  
19 the proposed key personnel have both a satisfactory level of transplant experience and an  
20 established history of transplant success for the specific organ type indicated in the application  
21 for designated transplant program status.

22  
23 MPSC recommendation of approval of a geographically isolated program that is not otherwise  
24 qualified does not give interim approval to the prospective program. The designated transplant  
25 program status of a geographically isolated program that is not otherwise qualified is effective  
26 only upon approval of the Board of Directors.

27  
28 For purposes of this provision, “geographically isolated” is defined as a program located entirely  
29 within a state or commonwealth noncontiguous with the mainland United States. This includes  
30 Alaska, Hawaii, and Puerto Rico.

31 #

**Public Comment Responses**

**1. Public Comment Distribution**

Date of distribution: 3/14/2014

Public comment end date: 6/13/2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	18	13 (93%)	0 (0%)	1 (7%)	4
Regional	11*	10 (91%)	0 (0%)	0 (0%)	0
Committee	19*	0 (0%)	0 (0%)	1 (50%)	17

\*Region 2 and the Pancreas Transplantation Committee, respectively, both had equal votes of support and opposition after discussing this proposal. See additional information below.

**2. Primary Public Comment Concerns/Questions**

The main theme among those in opposition to this proposal is the notion that exceptions for program approval undermine the importance of, and established Bylaws requirements for, the program approval process. OPTN Bylaws requirements for program approval are standards that have developed over time, and are accepted as measures to increase patient safety and quality outcomes. Accordingly, exceptions to program approval requirements may compromise patient safety at those programs with an exceptional approval.

A secondary recurring theme was a recommendation to define what constitutes “geographic isolation” to accommodate future scenarios instead of simply listing Alaska, Hawaii, and Puerto Rico as the only areas where this exception could apply.

**3. Regional Public Comment Responses**

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	12 yes, 0 no, 0 abstentions		In person
2	3/28/2014	11 yes, 11 no, 2 abstentions		In person
3	5/30/2014	17 yes, 0 no, 0 abstentions		In person
4	5/9/2014	23 yes, 0 no, 0 abstentions		In person
5	6/12/2014	21 yes, 4 no, 3 abstentions		In person
6	5/16/2014	52 yes, 0 no, 0 abstentions		In person
7	5/9/2014	22 yes, 0 no, 0 abstentions		In person
8	4/4/2014	9 yes, 3 no, 6 abstentions		In person
9	5/21/2014	15 yes, 0 no, 0 abstentions		In person
10	5/15/2014	20 yes, 0 no, 2 abstentions		In person
11	5/30/2014	19 yes, 2 no, 2 abstentions		In person

**Region 2:**

The members who opposed this proposal commented that a program should not be approved if they do not have a qualified surgeon. Allowing this could result in a patient safety issue.

**Committee Response:**

The MPSC is sensitive to potential patient safety concerns. As such, it should be noted that programs seeking this exception are not absolved of all expectations included in the OPTN Bylaws. The proposed Bylaws set up a process for the OPTN Board of Directors to consider approving programs in these geographically isolated areas. Before the Board would even be asked to consider approving these programs, the proposed Bylaws require geographically isolated applicants to “demonstrate to the MPSC that the proposed key personnel have both a satisfactory level of transplant experience and an established history of transplant success for the specific organ type indicated in the application for designated transplant program status.” If the MPSC had any concerns about geographically isolated applicant, then these applications would not be sent to the Board for its consideration.

**Region 4:**

The last sentence of the policy should be modified as follows: “For purposes of this provision, “geographically isolated” is defined as a program located entirely within Alaska, Hawaii ~~and~~ or Puerto Rico.”

**Committee Response:**

The MPSC appreciates your support of these additions to the OPTN Bylaws, and will include the simple language change that Region 4 provided.

**Region 5:**

- They were concerned that those applicable programs would have potentially low volumes and would subsequently not be held to the same standard for quality and outcome given their identified geographically challenging situation. They felt that there should be additional language added requiring a more stringent monitoring plan for these centers if granted approved under this proposal.
- They also felt that there needed to be a definition for geographically isolated. This type of situation is not specific to only those areas cited in the proposal – but there are many other areas that have geographical challenges. The policy should be written to allow the board to decide if the center is “geographically isolated” and not be restricted by naming specific areas in the proposal.

**Committee Response:**

The MPSC appreciates your support of these additions to the OPTN Bylaws. In response to the provided concerns, there is already a process for analyzing outcomes at low volume programs. An exceptionally-approved program with low volumes would be held to the same standard for analyzing outcomes at other low volume programs, in addition to all other Bylaws’ requirements such as those that address functional inactivity. Regarding how “geographically isolated” is defined, Committee discussion revealed a desire not to leave geographical isolation open to multiple interpretations. Ultimately, the MPSC decided that Alaska, Hawaii, and Puerto Rico are the only locations where this exception should apply, and explicitly stated this in the Bylaws to avoid any other possible interpretation of “geographically isolated.”

**Region 7:**

Members noted that CMS also has an exception clause for OPOs whose DSA includes Hawaii and Puerto Rico. They felt that this proposal aligned with that requirement.

**Committee Response:**

The MPSC appreciates your support of these additions to the OPTN Bylaws.

**Region 8:**

The members who opposed this proposal commented that if the purpose of the criteria are to provide quality and safety, why would the OPTN allow an exception? There was also a comment that the proposal is too specific. There will be another unique situation at some point and the committee and OPTN will have to send another proposal out for comment. This should be more general and the Board can access each request on a case by case basis.

**Committee Response:**

Whether or not the OPTN should consider granting an exception can only be made by the OPTN Board of Directors. The proposed Bylaws just set up a process for the OPTN Board of Directors to consider approving programs in these geographically isolated areas. If the OPTN believes making exceptions compromise quality and safety, then the request can be received and denied by the Board.

Regarding how “geographically isolated” is defined, Committee discussion revealed a desire not to leave geographical isolation open to multiple interpretations. Ultimately, the MPSC decided that Alaska, Hawaii, and Puerto Rico are the only locations where this exception should apply, and explicitly stated this. Predicting future unique situations is risky and the MPSC wants to limit the scope for invoking this process.

**Region 11:**

The region supported this proposal with the following comments:

- This proposal creates an exception due to a specific circumstance and is too restrictive. There should be a broader process on how to address exceptions.

**Committee Response:**

The MPSC appreciates your support of these additions to the OPTN Bylaws. In response to this being “too restrictive”, the Committee discussed this in-depth. Ultimately, the MPSC purposely decided that Alaska, Hawaii, and Puerto Rico are the only locations where this exception should apply, and explicitly stated this. Predicting future unique situations is risky and the MPSC wants to limit the scope for invoking this process.

**4. Committee Public Comment Responses**

**Pancreas Transplantation Committee:**

Committee members expressed a concern about creating the option for an exception when there are currently criteria in which transplant professionals and hospitals must abide by (i.e. the Bylaws and Policies).

Another member noted that the Pancreas Committee previously made recommendations to the MPSC about what constitutes inactivity for pancreas transplant programs, and this scenario seems to encompass a pancreas transplant program that is egregiously inactive.

A Committee member explained that he felt uncomfortable making such a large exception for a program that is clearly inactive.

A member suggested that programs, like the one the proposal is set up for, could be put on a probation status or a limited status with temporary approval.

The MPSC representative reiterated that the proposal is only to set up a process where the Board of Directors can receive an exceptional recommendation from the MPSC. The MPSC representative explained that he was confident, if the proposal was approved, there would be additional requirements (such as routine reporting of transplants and outcomes) for programs that utilize the exception process.

A HRSA representative pointed out that there is a large gap between the fixed criteria in the Bylaws and the appeals process for members may utilize should the member not fulfill the fixed criteria. Therefore, this proposal creates a narrowly construed middle ground in which non-compliant members have a process in which to be re-considered.

The Committee did not vote in support of the proposal. (4 yes; 4 no; 2 abstained)

**Committee Response:**

The proposed Bylaws set up a process for the Board of Directors to consider approving programs in the explicit geographically isolated areas and under defined conditions. If the OPTN believes making exceptions compromises quality and safety, then the request can be received and denied by its Board of Directors. Exception to approved program qualification criteria considerations cannot be made by the MPSC. If any transplant program is exceptionally-approved that program would still be held to the same standards for performance outcome results or functional inactivity as other transplant programs.

**Transplant Coordinators Committee:**

(Support 0, Oppose 13, Abstain 0) The Committee opposed this proposal as it is a patient safety issue and exceptions should not be allowed. Members agreed that if a center is not routinely doing transplants, patient care is compromised for donors and recipients. The Committee also agreed that annual competences need to be maintained by all transplant staff including surgeons and nurses.

**Committee Response:**

Whether or not the OPTN should consider granting an exception can only be made by the OPTN Board of Directors. The proposed Bylaws set up a process for the OPTN Board of Directors to consider approving programs in these geographically isolated areas. If the OPTN believes making exceptions compromise quality and safety, then the request can be received and denied by its Board of Directors. The comment regarding developing requirements for establishing competences for transplant staff evaluation is noted and will be addressed in future program qualification discussions.

## 5. Individual Public Comment Responses

### Comment 1:

*Vote: Oppose*

*Date Posted: 06/17/2014*

ASTS does not support this proposal as written. The qualifying criteria for key personnel have been developed over many years and are designed to provide the foundation for minimum program standards. Allowing a program to bypass these criteria based on geographic location is counterproductive to the creation and enforcement of unified OPTN policies.

### Committee Response:

The OPTN understands that when it approves qualifying criteria for key personnel, a minimum standard is established. It also understands that access to transplantation by patients in geographically isolated areas is viewed as being an important consideration when setting up patient care opportunities for those with end stage organ failure. Patient safety versus access concerns need to always be weighed and considered. The proposed Bylaws set up a process by which the OPTN Board of Directors may consider approving programs in defined geographically isolated areas. Before the Board would even be asked to consider approving these programs, the proposed Bylaws require geographically isolated applicants to “demonstrate to the MPSC that the proposed key personnel have both a satisfactory level of transplant experience and an established history of transplant success for the specific organ type indicated in the application for designated transplant program status.” If the MPSC notes during review any qualification concerns about geographically isolated applicant, then in accordance with this process that application would not be sent to the Board for its consideration. The proposed Bylaws provide an opportunity for the Board to carefully and deliberately enforce approved OPTN program approval criteria.

### Comment 2:

*Vote: Support*

*Date Posted: 06/16/2014*

In general the AST supports this proposal. In response to the specific request for comment, this does not appear to be a suitable setting to debate the appropriateness of current board approved qualification criteria, the details of which would need careful consideration prior to recommending removal of these criteria when considering approval for all transplant programs regardless of location. The current policy should be maintained for new program applications not considered geographically isolated as defined by proposal 12. Regarding patient safety, OPTN and the community as a whole will need to assume a higher potential risk to patient safety if a program is allowed to function without meeting all approval criteria and this risk must be balanced by the benefit of offering transplant services to individuals in isolated areas who may otherwise have no access to these treatments. In this regard, keeping patients fully informed should be a top priority. The following should be required of transplant programs operating as a result of this bylaw: 1) disclosure to ALL PATIENTS the nature of program approval via special consideration, including the specific reason(s) why board-approved criteria were not met, and the potential risk that may result, and 2) provision to all patients the location and contact information for the nearest transplant center offering the required services and meeting full board approved criteria. In addition the OPTN should consider a more rigorous protocol for monitoring outcomes than would otherwise be implemented for transplant programs meeting all board-approved acceptance criteria. It is not yet clear that the CUSUM / Bayesian reporting methodology would provide for early detection of "problematic" outcomes.

**Committee Response:**

The MPSC appreciates your support of these additions to the OPTN Bylaws. Regarding the AST's additional considerations, if the proposed process is approved the Board does have the opportunity to place patient notification requirements as a condition for exception-approval at one of these transplant program. The projected frequency of exception-approvals occurring under the conditions covered by this proposal is negligible. Over time if this exception-approval referral frequency is greater than initially foreseen then patient notification requirements can be added to future policy language. The current process for analyzing outcomes at low volume programs is expected to be adequate for identifying performance issues while new performance assessment methodologies emerge and are validated. An exceptionally-approved program with low volumes would be held to the same standard for analyzing outcomes as other low volume programs. These programs will also be subject to all other bylaws requirements that address functional inactivity.

**Post Public Comment Consideration:**

The Committee met via conference call on September 4, 2014, to review public comments received on the proposal. The Committee unanimously agreed to amend the proposal and remove the phrase "but not limited to" so that it is clear that only programs in Alaska, Hawaii, and Puerto Rico will be eligible for the exception to the bylaw. If it is later determined that other areas of the country should also have access to process introduced by these Bylaws, modifications will be pursued through the formal submission of another public comment proposal.