

At-a-Glance

Proposal to Allow a MPSC Recommendation to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area

- **Affected Bylaw:** Appendix A: Membership Application and Review of the OPTN Bylaws; A.3 Applying for Membership in the OPTN

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

The proposed bylaw language makes available a mechanism by which the MPSC may make a recommendation to the Board, and the Board may consider and approve the designation of transplant programs who currently cannot meet key personnel qualifying criteria because the applicant is located in a geographically isolated area. Currently, if an applicant cannot meet the program requirements, then the application is closed by the MPSC as rejected, leaving the applicant to appeal to the HHS Secretary for any further approval consideration of the closed application.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Candidates
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

This proposed bylaw is purposely limited in scope so it should only affect potential candidates in a defined community. The number of potential candidates would depend on the organ type and geographical area under consideration.

- **Compliance with OPTN Strategic Plan and Final Rule**

The proposal promotes the OPTN's Strategic Plan by promoting maximum capacity in providing donor organs transplanting and patients in isolated geographical areas by approving capable transplant program applicants who service such areas. The proposal also will clearly increase local access for patients seeking end stage organ disease treatment which otherwise might not be available due to their place of residence. Transplanting in geographical isolation is one of these situations and the reason for this proposed bylaw is to address any unintended disadvantages encountered

by transplant hospitals operating in such conditions.

- **Specific Requests for Comment**

When you consider and comment on the entirety of this proposal the committee is interested in whether or not the community feels it is appropriate for the OPTN to move away from Board approved qualification criteria when designating and approving a transplant program regardless of its location? Are the patients being served safely in these cases if approval criteria are not fully met by the applicant?

Proposal to Allow a MPSC Recommendation to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area

Affected/Proposed Policy: Appendix A: Membership Application and Review of the OPTN Bylaws; A.3 Applying for Membership in the OPTN

Membership and Professional Standards Committee (MPSC)

Public comment response period: March 14 – June 13, 2014

Summary and Goals of the Proposal

The proposed bylaw language makes available a mechanism by which the MPSC may make a recommendation to the Board, and the Board may consider and approve the designation of transplant programs who currently cannot meet key personnel qualifying criteria because the applicant is located in a geographically isolated area. Currently, if an applicant cannot meet the program requirements, then the application is closed by the MPSC as rejected, leaving the applicant to appeal to the HHS Secretary for any further approval consideration of the closed application.

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 proposed key personnel who had successfully (defined as the closed pancreas transplant program never appeared before the MPSC for any patient safety or compliance related issues and never received OPTN sanctions) performed pancreas transplantation at a now closed Hawaiian transplant hospital. The original pancreas transplant program was approved in 1992 and pancreas transplant surgery had been performed there continuously under the direction of the new program's proposed primary surgeon until its closure in December 2011. In addition to the primary surgeon, a majority of the pancreas transplant staff from the closed transplant hospital moved to the applicant facility. The submission of a new pancreas transplant program application was mandatory and the MPSC was required to review it for compliance using current approved program designation and approval requirements. While the proposed primary surgeon met pancreas program training or experience transplant volume requirements back in 1992, he no longer met the requirements.

A major reason for this is the limited opportunity to perform a large enough volume of pancreas transplants in a geographically isolated area such as Hawaii to meet or maintain primary pancreas surgeon qualifying criteria. The average number of pancreas transplants historically performed in Hawaii was less than two a year.

Many MPSC members expressed the opinion that since essentially the same pancreas transplant team which led the pancreas transplant program at the closed transplant hospital would be the basis for the new hospital's program and the committee is not allowed to recommend approval of a non-qualifying transplant program application, the MPSC should be able to recommend that the Board consider approving this applicant given prior success and a lack of opportunity to perform pancreas transplants due to geography. No mechanism existed for the MPSC or the Board of Directors to do this, thus the proposed bylaw.

Committee staff was asked to research and offer an opinion regarding the feasibility of either using as is or amending OPTN Bylaw D.10.F. Relocation or Transfer of Designated Transplant Programs in cases such as this. Staff strongly advised against using or amending this bylaw provision. Under this provision both parties must be currently active and approved OPTN members for a program transfer to occur.

Significant Features & Issues Regarding This Proposal

- This bylaw language covers transplant program designation and consideration for all organ types.
- “Geographically isolated” is precisely defined in regards to context, intent and application of this provision to apply only to Alaska, Hawaii, and Puerto Rico. The aim is to remove any ambiguity or misunderstanding regarding what constitutes a geographically isolated condition for this exception consideration.
- An applicant’s inability to meet current key personnel requirements is the only program approval criteria which can be re-examined for special consideration. Proposed key personnel assessment standards which can be used in deciding a satisfactory level of transplant experience is purposely left undefined in the bylaw. It is a subjective peer criterion.
- The language existing in this bylaw letting reviewers determine what is a satisfactory level of transplant experience for the proposed primaries and how to define a established history of transplant success for the specific organ type under consideration is recognized by the authors to be challenging. The intended definition of success is for an applying program (personnel) must have demonstrated previous transplant experience as a unit free from any MPSC and OPTN imposed sanctions for performance and compliance related issues.
- Exceptions to or variances from 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.
- A MPSC recommendation to the Board for consideration of a non qualifying applicant for transplant program approval under this proposed bylaw does not convey designation or interim approval of a program. A new transplant program designation and approval and transplantation can only occur after the Board grants final approval.
- The bylaw is intended for very limited use. Transplant hospitals not meeting the geographically isolated definition in this provision should not be permitted to make new program or key personnel change application using it.
- Transplant program qualification requirements are Board approved minimum standards which are intended to facilitate safe and successful transplantation. To allow for a lower program approval standard may not be in the best interest of the patient living in the geographically isolated area defined as Alaska, Hawaii, and Puerto Rico.

Expected Impact on Living Donors or Living Donation

If the proposed new organ transplant program has a living donor option the expected impact is large. This proposal could allow for patients seeking a living donor to be treated at their local transplant hospital that may not be approved under the current Bylaw requirements. Board consideration of a living donor recovery component at an OPTN member hospital in Alaska, Hawaii, and Puerto Rico is allowable if the transplant program is designated and approved under this provision.

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 it is not being served, the expected impact of approving a safe and successful transplant program is substantial. Actual numbers are dependent on the end stage organ disease being considered for transplant.

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

The following two OPTN Strategic Goals and Priorities are impacted by this proposal:

- **Maximum Capacity** – The proposed changes will help to maximize the number of donors and transplants by allowing the Board to consider approving capable transplant program applicants who serve a defined geographically isolated area.
- **Increase Access** – The designation and approval of capable transplant programs in Alaska, Hawaii, and Puerto Rico 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 bylaw is to address any unintended disadvantages to transplant hospitals and its patients living 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 consideration and approval process. This monitoring will also include documenting 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 and the Board upon request.

Additional Data Collection

Any additional data collection is described immediately above. The possibility does exist for patient notification requirements to be added at a later date regarding disclosure of when exceptional considerations are invoked and program approval given.

Expected Implementation Plan

The proposed change will not require members to alter their policies or procedures. Members will continue to submit complete new transplant program applications to the OPTN for review. The proposal clearly identifies situations when an applicant's proposed primary surgeon and/or physician cannot qualify due to the member being geographically isolated and allows for this application to be forwarded to the Board of Directors for approval exception consideration.

This proposal will not require programming in UNetSM.

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in November, 2014 and, if approved, will become effective on February 1, 2015.

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 allowing for this additional approval recommendation option along with its conditions.

Compliance Monitoring

This proposal does not alter the review of new transplant program applications for designation and approval as conducted by the MPSC. It allows for the referral of non qualifying transplant program applications in defined geographically isolated locations by the MPSC to the Board of Directors for approval consideration. All MPSC decisions regarding the qualification of primary surgeons and physicians will be handled and reviewed using current Bylaw requirements. Each situation will be handled independent of any prior decisions and not be implemented until a Board approval is granted.

Policy or Bylaw Proposal

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

OPTN Bylaws Appendix A Membership Application and Review, Section A.3

A.3.F. Geographically Isolated Transplant Program Applicants

The MPSC may recommend to the Board of Directors the approval of a designated transplant program if the prospective program cannot satisfy the current key personnel requirements due to its geographical isolation. Geographically isolated applicants must 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.

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

For purposes of this provision, “geographically isolated” is defined as a program located entirely within Alaska, Hawaii, and Puerto Rico.