

## Briefing Paper

# Changes to Islet Bylaws

*OPTN/UNOS Pancreas Transplantation Committee*

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# Changes to Islet Bylaws

<i>Affected Policies:</i>	<i>OPTN Bylaws Appendices D.6 (Transplant Program Director), D.7 (Transplant Program Key Personnel), D.7.A (Primary Transplant Surgeon and Physician), D.8 (Changes in Key Transplant Program Personnel), D.11 (Review of Transplant Program Functional Inactivity), D.12 (Additional Transplant Program Requirements), G (Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs), G.4 (Requirements for Designated Pancreatic Islet Transplant Programs), G.5 (Primary Pancreatic Islet Transplant Surgeon Requirements), G.6 (Primary Pancreatic Islet Transplant Physician Requirements), K.1 (Transplant Program Inactivity)</i>
<i>Sponsoring Committee:</i>	<i>Pancreas Transplantation Committee</i>
<i>Public Comment Period:</i>	<i>August 3, 2018 – October 3, 2018</i>
<i>Board of Director's Date:</i>	<i>December 3-4, 2018</i>

## Executive Summary

Current islet Bylaw personnel requirements do not reflect the need for islet transplantation experience and expertise. This may prevent qualified candidates from leading programs and could prevent the field from growing. Inappropriate requirements may be harmful to patients if personnel who are inexperienced in islet transplantation oversee islet programs and islet patient care.

The OPTN/UNOS Pancreas Transplantation Committee (the Committee) has developed new requirements for islet programs that reflect the needs particular to islet programs and their patients. Currently, the OPTN Bylaws *Appendices G.5: Primary Pancreatic Islet Transplant Surgeon Requirements* and *G.6: Primary Pancreatic Islet Transplant Physician Requirements* specify requirements for islet program key personnel that are identical to pancreas program requirements despite significant differences in the experience and backgrounds of key islet personnel. The overarching goals in seeking to improve islet program Bylaws are to provide a simple, achievable experiential pathway for islet program leaders that facilitates the initiation and development of clinical islet transplant programs, while ensuring sufficient experience to provide for safe patient care. The proposed changes include three critical elements:

1. Require a single clinical leader of the islet program to replace the transplant surgeon and transplant physician roles. This person must have experience inclusive of pre-, peri- and post-operative care, islet isolation, and a demonstrated background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology.
2. Require four different expert medical personnel roles with defined skill sets to provide key support in the delivery of islet transplant therapy: an abdominal surgeon, portal vein access specialist, immunosuppression management specialist, and endocrinologist. A single person can fill one or more of the aforementioned roles.
3. Permit islet transplant programs to be free standing and not affiliated with an established pancreas transplant program. Allowing free-standing islet programs reflects the difference in background and experience for islet program personnel compared to pancreas program personnel.

The proposed changes apply only to programs that perform allogeneic islet transplants. Bylaw program requirements that provide accountability and reflect the necessary expertise and experience in program personnel promote patient safety. Changing the Bylaws to provide more flexibility for islet programs while enhancing program accountability with more detailed islet experience requirements should contribute positively to increased transplant recipient safety.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

Because islet programs are directly impacted, the Committee appreciates any feedback from islet program personnel on the proposed changes. In particular, the Committee requests feedback on the following two questions:

1. The proposal requires islet programs to have a clinical leader who meets islet-specific requirements including experience with islet isolation, pre- peri- and post- operative care, and completion of a clinical fellowship in a related field (transplantation medicine or surgery, immunosuppression management, beta cell biology, or endocrinology). Should anything be added or removed from these requirements?
2. Currently, islet programs are required to be at the same hospital as a pancreas program, or meet exception requirements specified in *Appendix G.4.D: Programs Not Located at an Approved Pancreas Transplant Program*. This proposal would allow islet programs to be free-standing from pancreas programs. Do members support or have concerns about this change?

Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community.

## What problem will this proposal address?

OPTN Bylaws for islet key personnel do not require that applicants have islet transplantation experience and expertise. Currently, the OPTN Bylaws *Appendices G.5: Primary Pancreatic Islet Transplant Surgeon Requirements* and *G.6: Primary Pancreatic Islet Transplant Physician Requirements* specify requirements for islet program key personnel that are identical to pancreas program requirements despite significant differences in the experience and backgrounds of key islet personnel. This may allow unsuitable people to lead islet transplant programs and prevent qualified physicians from leading programs, hampering development of the field. Indeed, qualified physicians have been denied leadership positions in islet programs because, despite significant islet transplantation experience, they lack experience in current pancreas transplantation requirements.<sup>1</sup> Inappropriate requirements may be harmful to patients if personnel who are inexperienced in islet transplantation oversee islet programs and islet patient care.

## Why should you support this proposal?

Bylaw requirements for islet program personnel should reflect an expertise and background in islet transplantation to best support islet transplantation candidates and recipients. Pancreas transplantation is substantially different from islet transplantation in terms of necessary experience and expertise, yet leaders of islet programs must currently meet pancreas transplantation experience requirements. This proposal directly addresses the problem identified by the Committee by creating requirements for clinical leaders of islet programs that reflect the specific needs of islet programs and include islet transplantation experience, helping to ensure that islet transplantation candidates and recipients receive the appropriate level of care from their providers.

## How was this proposal developed?

Since 2013, the MPSC and the Pancreas Committee have been reviewing pancreas and islet transplant program Bylaws for currency and clarity. Though a Joint Societies Working Group developed recommendations in 2015, the project did not move forward at that time. A subsequent MPSC proposal in 2015 addressed changes to pancreas program requirements.<sup>2</sup>

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<sup>1</sup> 2018 OPTN data. Obtained June 25, 2018.

<sup>2</sup> "Changes to Transplant Program Key Personnel Procurement Requirements." OPTN/UNOS Policy Notice, December 23, 2015.

In 2017, the MPSC encouraged the Pancreas Committee to resume work on this project. The MPSC noted that the Bylaws require islet program primary surgeons to have identical background and experience as pancreas program primary surgeons, without consideration of islet transplantation training and experience. The Committee agreed it would be appropriate and timely to review the Bylaws pertaining to islet programs.

The Islet Bylaws Subcommittee (the Subcommittee) met throughout the fall 2017 and spring 2018 to develop through clinical consensus a proposal that identifies the appropriate personnel and requirements for islet programs. The Subcommittee included leaders in the islet transplantation field to ensure the relevant expertise in the subsequent discussions. Key to the Subcommittee's discussions was a desire to improve flexibility while increasing accountability for islet programs. For example, the Subcommittee supported replacing the primary surgeon and primary physician roles with one leader of the islet program. This person would have more extensive islet transplant experience, but fulfill a role previously fulfilled by two positions: the primary surgeon and primary physician.

The Subcommittee also supported requiring, instead of recommending, expert medical personnel to be present on site at islet programs. The Committee agreed that the Bylaws should be explicit about requirements and avoid recommendations, which fail to give members clear direction. Adding an abdominal surgeon, surgeon or interventional radiologist with experience in portal vein access, and physician to handle immunosuppression, made the expert medical personnel more islet-specific. While increasing accountability by requiring programs to have islet-specific expert medical personnel, the Subcommittee also supported flexibility by allowing one individual to fulfill multiple roles if that individual meets the requirements to be a clinical leader or expert medical personnel.

The Subcommittee also reviewed the Bylaws both for improvements and consistency with current compliance requirements. For example, the Subcommittee supported allowing biologics lab applications (BLAs) for islet facilities; while investigational new drug (IND) applications are currently specified, some islet programs have BLAs, which are FDA-approved. The decision to allow free-standing islet programs (as opposed to islet programs associated with pancreas transplant programs) is consistent with this approach to encourage flexibility and accountability. Allowing free-standing islet programs reflects the difference in background and experience for islet program personnel compared to pancreas program personnel.

Having determined the core changes to the islet Bylaws, the Subcommittee presented the Committee and MPSC with the proposed changes and received positive feedback. In response to questions, the Subcommittee clarified that expert medical personnel are not primary personnel, but serve supporting roles in the islet program. The Committee also informed the Collaborative Islet Transplant Registry (CITR) of the proposed changes, and issued an update to the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) organizations.

The Committee voted unanimously on May 31, 2018 to send the proposed changes out for public comment.

## **How well does this proposal address the problem statement?**

The Committee identified several areas of islet Bylaws that could be improved to increase flexibility, accountability, and better reflect the needs of islet programs and their patients:

1. Primary personnel
2. Expert medical personnel
3. Free-standing islet programs

Each area of improvement is discussed in more detail below. These improvements reflect the clinical consensus achieved by a Subcommittee led by leading islet experts in the field, and including various

perspectives by pancreas transplant surgeons, transplant administrators, and other members of the community.

### 1. *Primary personnel*

Currently, both pancreas and islet programs require two primary personnel members, a primary physician and a primary surgeon, that meet the pancreas program personnel requirements described in OPTN Bylaws Appendices *G.2: Primary Pancreas Transplant Surgeon Requirements* and *G.3: Primary Pancreas Islet Transplant Physician Requirements*. The Subcommittee determined that islet programs could be led appropriately by one individual instead of two, but this individual should have more islet-specific experience.

The rationale for this change is to simplify the leadership authority. The Committee agreed that it was not necessary to have both a surgeon and a physician as primary leaders because the minimum required role for a surgeon would be to handle abdominal complications (e.g. bleeding, portal vein thrombosis, liver abscess, other surgical complication of the transplant procedure) and this role could be filled by expert medical personnel. What is more important than having both a physician and surgeon lead the islet program is having one person who has substantial experience that demonstrates the necessary expertise in islet transplantation.

The leader of the islet program must be a clinician who holds an MD or equivalent and is credentialed to treat patients. The leader must be either a physician or a surgeon who has demonstrated involvement in the management and care of at least six islet transplant patients. Of these, at least one patient must be an allogeneic islet transplant patient. The decision to require management and care of six patients was determined as a compromise between having the requisite experience needed to lead the program while not requiring a prohibitive number of patient-direct care that would unnecessarily limit the growth of the field. The leader's experience must include observation of three islet isolations, of which at least one must be an allogeneic islet isolation.

Allogeneic islet transplantation involves transplantation of islet cells from an individual other than the transplant candidate. Autologous islet transplantation involves transplantation of islet cells from the transplant candidate, meaning no immunosuppression is required. While autologous islet transplants may count towards the clinical leader requirements, the islet Bylaws only apply to programs that perform allogeneic islet transplants, which is why clinical leaders must demonstrate specific allogeneic islet transplant experience in addition to any autologous islet experience.

The leader of the islet program would also be required to have a background demonstrating expertise in a field related to islet transplantation: transplantation medicine, immunosuppression management, beta cell biology, or endocrinology. Applicants seeking to fill this role for an islet program would have to submit with their application a personal letter detailing their background, as well as a letter of support from either the Chief or Chair of their program and a letter of endorsement from an islet transplant clinician from another program. The person filling this role would need the same hospital practice credentialing requirements described in the OPTN Bylaws Appendices *G.2: Primary Pancreas Transplant Surgeon Requirements* and *G.3: Primary Pancreas Islet Transplant Physician Requirements*, depending on whether they are a surgeon or physician. The islet program leader must document a clinical fellowship lasting at least six months in transplantation medicine, transplantation surgery, immunosuppression management, beta cell biology, or endocrinology.

These changes directly address the problem identified by the Committee by creating more detailed and islet-specific experience and expertise for the islet leader requirements.

### 2. *Expert Medical Personnel*

Currently, OPTN Bylaws Appendix *G.4.B: Expert Medical Personnel* recommends islet programs have adequate access to an endocrinologist, someone with experience in complying with FDA regulations and

an individual with experience isolating islets. The Committee proposes that islet programs be required to have certain expert personnel on site at their hospital:

- An abdominal surgeon to treat procedural complications
- A surgeon or interventional radiologist who has performed at least three portal vein access procedures and has approval by the hospital credentialing committee to perform portal vein access procedures
- A physician to manage immunosuppression (a minimum of six immunosuppression management cases)
- An endocrinologist or physician to oversee transplant metabolic outcomes

In addition to these required personnel, islet programs must have access to or have integrated into their program a person with experience in FDA compliance, a diabetes educator, and a scientist with experience in islet quality assessment. The Committee proposes requiring certain expert personnel be on site because these personnel are essential to the function of the islet program and the safety of islet transplant patients. However, the Committee considers it possible that some programs may have one person fulfill multiple or all roles, and clarifies in the Bylaws language that one person fulfilling multiple roles is acceptable. In addition, the leader of the islet program may fulfill one or more roles of the expert medical personnel.

The proposed changes provide flexibility for islet programs in having one individual fulfill multiple roles, while still requiring more detailed and islet-specific experience for islet program support personnel. These roles reflect the Committee's assessment of the essential personnel for an islet program to adequately support and care for islet patients.

### 3. *Free-standing islet programs*

Currently, islet programs must be either at the same hospital as a pancreas transplant program or meet an exception and maintain a relationship with one, as detailed in OPTN Bylaws Appendix *G.4.D: Programs Not Located at an Approved Pancreas Transplant Program*. The Committee considered recreating the requirement to be at or have an association with a pancreas transplant program, but members agreed that it may be too restrictive to require affiliation with a pancreas transplant program as more pancreas programs close (16 voluntarily withdrew in the last 4 years – 2014 to 2017), and allowing free-standing islet transplant programs would still be considered safe practice.<sup>3</sup> This is consistent with the work of the Committee to create a different path for islet programs.

The Committee also considered that there are already many challenges to starting a program, and requiring an association with pancreas transplant programs might unnecessarily restrict an institution's ability to establish an islet transplant program. With the exception of VCA programs, no other membership requires affiliation with another transplant program.<sup>4</sup> Therefore, the Committee proposes allowing islet transplant programs to be free-standing without associations with pancreas transplant programs.

The changes to the Bylaws proposed by the Committee provide enhanced accountability for islet-specific experience while increasing flexibility for islet program personnel to fulfill multiple roles and eliminating the requirement that islet programs have an association with a pancreas program. This increased accountability and flexibility ensures that islet programs have the appropriate level of care and oversight in essential personnel.

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<sup>3</sup> 2018 OPTN data. Obtained July 23, 2018.

<sup>4</sup> OPTN Bylaws. *Appendix D.2: Designated Transplant Program Requirement*. Accessed July 23, 2018.

## Was this proposal changed in response to public comment?

The proposal was not substantively changed in response to public comment. To be consistent with other member personnel requirements, the language was updated to reflect the requirement to document experience in a log, and language was also clarified to indicate that direct involvement in patient care would be considered cumulatively. Two minor changes were removing duplicative language and making sure consistent terms were used for the islet transplant program. Overall, public comment showed broad support for the proposal and the approach of the Committee to address differences in islet transplantation that should be reflected in the requirements of their personnel. Below is a summary of the public comment feedback.

### Public Comment Feedback

The transplant community reviewed the proposal during public comment from August 3, 2018 to October 3, 2018. All 11 regions supported the proposal (see Table 1), which was on consent at regional meetings. The American Nephrology Nurses Association (ANNA), American Society for Histocompatibility and Immunogenetics (ASHI), American Society of Transplantation (AST), and Associations of Organ Procurement Organizations (AOPO) issued public comments in support the proposal.

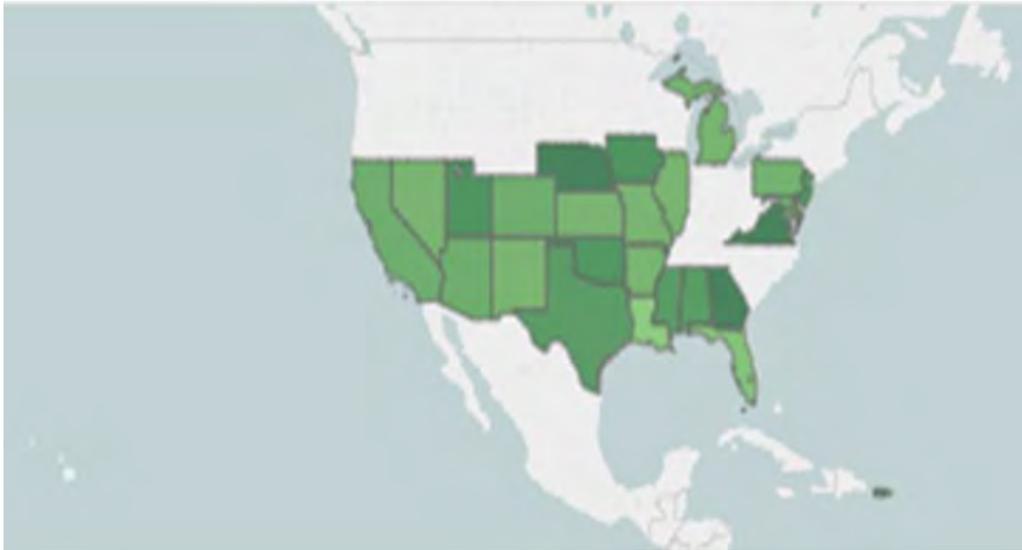
**Table 1: Regional Feedback\***

Region	Vote	Support/Oppose
1	4-8-1-0-0	Support
2	8-24-2-0-0	Support
3	12-12-8-1-0	Support
4	19-9-2-0-0	Support
5	11-18-4-0-1	Support
6	26-17-1-1-0	Support
7	11-11-5-0-0	Support
8	11-0-3-0-0	Support
9	8-10-2-1-0	Support
10	10-12-2-1-2	Support
11	8-14-1-0-0	Support

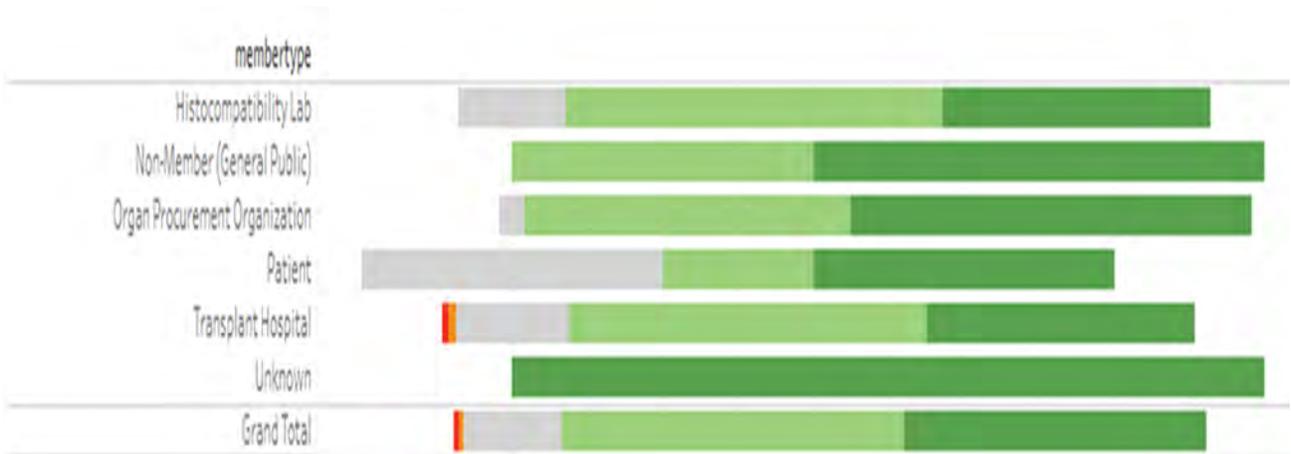
*\*From left to right the votes were tallied accordingly: Strongly support – support – abstain/neutral – oppose – strongly oppose*

Across member types and geographic area, support was also consistent. Figures 1 and 2 show sentiment by state and by member.

**Figure 1: Sentiment by State**



**Figure 2: Sentiment by Member**



Ultimately, feedback focused on changes to personnel requirements and the allowance of free-standing islet programs. The Committee also reviewed small changes to the language based on suggestions from UNOS staff. The following sections address public comment feedback, committee discussions and post-public comment review of the Bylaws language.

**1. Changes to Personnel requirements**

Commenters that supported the proposal cited that the proposal would better align personnel requirements with the needs of islet programs, leading to better suited candidates in key positions. Commenters noted that it would make sense to differentiate islet requirements from pancreas requirements because islet transplantation is a different undertaking. Commenters also expressed support for simplifying the administrative duties by requiring one clinical leader instead of two primary surgeon and primary physician roles.

In its review of the proposal, the Membership and Professional Standards Committee (MPSC) asked whether there were risks to patients by allowing a free-standing islet program that doesn't have to have a transplant surgeon present. The proposed Bylaws would require an abdominal surgeon on staff at the islet transplant program; however, that individual does not need to be a transplant surgeon. The

Committee did not want to limit islet programs that may have an individual who had necessary surgical experience to handle complications but is not specifically a transplant surgeon. The Committee also clarified for the MPSC that the free-standing islet program would still need an affiliation with an OPO because the same general transplant program requirements would apply to these islet transplant programs.

The American Society of Transplant Surgeons (ASTS) opposed the proposal and expressed concern that the personnel requirements should include a transplant surgeon with pancreas procurement experience. The Committee discussed at length whether to include a transplant surgeon, and determined it would not be necessary from a patient safety or outcomes standpoint, and indeed could harm patient access if it prevents islet programs from growing and prevents qualified individuals from supporting islet programs. The Committee considers that the requirements for an abdominal surgeon and individual to handle immunosuppression sufficient to ensure adequate support handling potential post-transplant complications and providing care to the patient. The additional islet-specific requirements of the clinical leader supports a program having the sufficient collective experience to address patient safety concerns.

## 2. Free-standing islet programs

In the proposal that was distributed for public comment in August, the Committee asked the community whether it agreed with the change to allow free-standing islet programs. APOPO wrote strongly in support of free-standing islet programs, noting that this change could expand islet transplantation, which improves patient lives and increases utilization of pancreata.

The MPSC asked what the original rationale for having islet programs be connected to pancreas programs. The Pancreas Committee chair presenting the proposal noted that this requirement stemmed from making sure patients have both options of pancreas and islet transplantation presented to them. When the Committee reviewed the public comment feedback at its in-person on October 29<sup>th</sup>, Committee members agreed that explaining alternative therapies is an expectation given to pancreas and islet programs regardless. For example, pancreas programs without an islet program should still provide patients with a descriptive of that option in case patients are interested in pursuing an islet infusion in lieu of a pancreas transplant. Thus, it is not necessary to have islet programs housed with pancreas programs simply because patients need to hear all their options. It is an expectation on the part of the transplant program, whether islet or pancreas, to help the patient make the best decision based on their particular set of circumstances and perspective.

There were two comments that expressed concern about free-standing islet programs, including the comment from ASTS. The concern centered on the potential negative impact on patient safety by allowing islet programs to not have an association with a pancreas program. The Committee seriously considered whether it was appropriate to have free-standing islet programs. By making a more robust personnel requirement structure at islet programs, the Committee considers that the concerns about patient safety will not be borne out. Instead, an islet program will have to staff personnel with more islet specific experience, while still having the surgical expertise in an abdominal surgeon and a physician to handle immunosuppression, roles that figure prominently in pancreas transplant programs. As mentioned in the previous paragraph, the Committee did not feel it sufficient that islet programs could fail to mention pancreas transplantation as an option to not allow free-standing islet programs; there is an expectation that would extend to islet programs that they discuss with their patients all of the viable options for treatment. Because of these reasons, and overwhelming support for the changes in general, the Committee declined to modify the section allowing free-standing islet programs.

## 3. Modifications the Committee did make

Based on feedback from UNOS staff, the Committee added standard language indicating that the clinical leader's experience of the management and care of patients must be documented in a log. A sentence requiring pre-, peri- and post-transplant care was removed because it was already implied by the direct involvement that the clinical leader must meet. Direct involvement in patient care was clarified to apply cumulatively to the six islet patients.

The Committee voted on language that made consistent the use of “islet transplant program” instead of “islet program” and “islet” instead of “pancreatic islet.” The third paragraph in *K.1: Program Director and Clinical Leader* that specified requiring a report from the hospital credentialing committee on the clinical leader was deleted because it was duplicative of the third requirement in *K.2: Islet Transplant Program Clinical Leader Requirements*.

With these minor, non-substantive changes to the proposal, the Committee voted unanimously to send the proposed Bylaws language to the Board.

#### 4. Outreach to Islet Program Leaders

The Committee reached out to the Collaborative Islet Transplant Registry (CITR) both before and during public comment for feedback. The proposal was distributed to CITR; however, no feedback was submitted through public comment. Because the proposal represents a significant change in the personnel requirements of islet programs, and because the CITR members had not weighed in during public comment, the Committee reached out individually to leaders in the islet community to see if the proposal would have any adverse impacts on their programs. The two responses from that post-public comment outreach effort indicated that the individuals supported the changes and thought they were reasonable. Given the effort the Committee has taken to inform CITR and reach out to its members, the Committee appreciates that the potential impact on islet programs has been assessed as successfully as possible prior to Board review.

## Which populations are impacted by this proposal?

The proposed changes have the potential to impact every islet transplant program and each islet transplant candidate by ensuring qualified personnel are performing islet transplantations.

## How does this proposal impact the OPTN Strategic Plan?

*Increase the number of transplants:* If the proposed changes make it easier for appropriately qualified islet personnel to qualify as primary personnel, the number of islet programs may increase. Since there are very few islet programs, any increase in number could improve patient access by decreasing the average patient’s distance from an islet program, potentially leading to an increase in islet transplant candidates and the number of islet transplants performed.

*Improve equity in access to transplants:* Since there are very few islet programs, any increase in number could improve patient access by decreasing the average patient’s distance from an islet program, increasing equity in access to transplants.

*Improve waitlisted patient, living donor, and transplant recipient outcomes:* Bylaw changes have the potential to impact every islet transplant program which will indirectly impact each candidate waiting for an islet transplant by ensuring qualified personnel are performing islet transplantations and providing patient care, resulting in improved outcomes for transplanted patients.

*Promote living donor and transplant recipient safety:* Bylaw program requirements that provide accountability and reflect the necessary expertise and experience in program personnel serve to promote patient safety. Changing the Bylaws to provide more flexibility for islet programs while enhancing program accountability with more detailed islet experience requirements should contribute positively to increased transplant recipient safety.

*Promote the efficient management of the OPTN:* No expected impact on this goal.

## How will the OPTN implement this proposal?

The OPTN will communicate with members the new requirements in Transplant Pro and publishing of policy notices. Since this proposal needs Office of Management and Budget (OMB) approval, the OPTN will let the community know after the OMB has approved the proposal and provide members with a schedule when the expected changes will be implemented.

This proposal will require programming in UNet<sup>SM</sup>.

If approved by the OPTN/UNOS Board of Directors, the proposed Bylaws will be implemented pending programming and notice to members. Upon implementation, only transplant hospitals with an islet transplant program that has been approved based on a demonstrated compliance with the proposed Bylaws will be permitted to register and transplant islet candidates.

Implementing these Bylaws will require a new islet transplant program application form to be created in the UNOS membership system. The OPTN must also submit the islet transplant program application forms to the OMB for approval before distributing the forms to members. Upon completion of programming and OMB approval of the application forms, the OPTN will provide a 30-day advance notice of a 90-day application period for members to complete and submit OPTN islet transplant program applications. Once the application period is announced, UNOS will send an application to each transplant hospital with an approved islet transplant program so the program can reapply for approval under the new membership criteria. Transplant hospitals that do not receive an application but wish to apply for an islet transplant program should contact the UNOS Membership Analyst for their region to obtain an application and the necessary instructions once the application period is announced.

The proposed Bylaws will be slated for implementation 90 days after the conclusion of the 90-day application submission period. During these 90 days, UNOS and the MPSC will process each application received before the submission deadline. Members will be alerted of the status of all processed applications before the implementation date. Specifically, applying hospitals will be told either that the MPSC will recommend that the Board of Directors approve their islet program or that their application has been rejected and the reason why.

Every application received during the application submission period will be acted on prior to the implementation of the proposed Bylaws. Islet transplant program applications submitted after the end of the submission period will be processed in the order they are received. UNOS and the MPSC will try to act on every application received before the proposed Bylaws' implementation date; however, applications received after the submission deadline might not be processed before the implementation date. Timely submission of a transplant hospital's islet transplant program application will be critical in obtaining program approval before the implementation of the Bylaws.

Implementation and ongoing efforts among all departments are classified as medium. This would include the new transplant application process described above, related IT programming work, intake and review of transplant program applications, and processing key personnel changes that occur over time.

## How will members implement this proposal?

### Transplant Hospitals

If the proposal is approved, membership applications will be updated to reflect the changes to the requirements for islet personnel, which transplant hospital personnel would have to meet and document in order to be eligible for those positions (specifically, the clinical leader and expert medical personnel positions). Islet programs will have separate membership applications from pancreas programs.

Any transplant hospital that intends to perform allogeneic islet transplants after implementation of these proposed Bylaws must complete and submit an islet transplant program application to the OPTN during

the application submission period. Transplant hospitals that currently have an approved islet transplant program must submit one of the following to the OPTN during the application submission period:

- A completed islet transplant program application
- An opt out form indicating that the hospital will be voluntarily inactivating or withdrawing approval of its islet transplant program according to *OPTN Bylaws Appendix L: Transplant Program Inactivity, Withdrawal, and Termination*

This proposal may impact existing islet programs differently than new islet programs.

- Existing programs: Transplant hospitals will need to assess if the viability of the islet cell transplant program lends to reapplying with the OPTN. If current personnel meet the minimum training and experience requirements, administrative time by way of re-application would be required, potentially two to three months depending on preparation and levels of review prior to submission to the OPTN. This may be between \$1,500-\$4,500.

If current personnel do not meet the proposed minimum training and experience requirements, the hospital may need to recruit individuals who meet the requirements; even with shared roles there could be considerable cost associated with this effort. The application time would be longer and take six to twelve months. Staffing costs could be substantial for the program that needs to recruit qualified individuals, perhaps \$550,000-\$850,000. These initial costs cannot be passed through to payers or distributed across organ acquisition costs as the initial costs would be investments in the program. Future payer contract negotiations may see an increase in contractual amounts, but this would not be seen in the short-term. If the program is unable to identify a qualified individual, this would require closing their program which will impact case volume and revenue.

In considering the impact of implementing this change, the Committee reached out to current islet program directors to identify if they anticipated that additional personnel would need to be hired at their facilities. No program directors identified this as a problem. While the costs estimated to hire additional personnel could be incurred by existing programs, it is important to note that no islet programs responded during public comment or after that this was a potential concern.

- New programs: Transplant hospitals that intend to apply for a new islet transplant program may need to identify a qualified individual who meets the training and experience requirements. If one individual could fulfill two roles, there would be a reduced overall cost. If not, there could be increased costs to recruit providers to fulfill each required role. The application time for new programs would be longer than an a hospital with qualified personnel due to recruiting, hiring, training, etc..., and take six to twelve months. There would also be costs associated with starting a new program, e.g.: capital purchases, potential for additional FTE(s), clinic space, etc... Transplant costs would decrease if case volume increases as is the purpose of this proposal.

Administrative time associated with the application process would be seen (perhaps in the range of 35-40 hours), SOPs and staff training on the same. Initial costs per case would increase, though this would decrease over the long term.

Ongoing costs would include administrative and operational costs of operating an islet cell program, and would be reflective of case volume. The largest component of this would be direct costs associated with expert medical personnel potentially from \$500,000-\$1,200,000/year (total compensation, malpractice insurance, etc...). Administrative costs would be very low by comparison, perhaps \$5,000/year.

### **OPOs and Histocompatibility Laboratories:**

This proposal will have no operational or fiscal impact on transplant programs or histocompatibility laboratories.

## Will this proposal require members to submit additional data?

Yes, additional data collection will be required because of this proposal. The supporting principles of data collection are to determine member-specific performance and to ensure patient safety when no alternative sources of data exist. This proposal will change the data that islet programs submit in order to better reflect the expertise of the necessary islet program personnel. Requiring data related to islet-specific expertise will help ensure patient safety.

## How will members be evaluated for compliance with this proposal?

The MPSC will review islet transplant program applications to determine compliance with the proposed Bylaws. Upon implementation, UNOS will facilitate the key personnel change process and the MPSC will review key personnel change applications to ensure ongoing compliance with the Bylaws when changes to an islet transplant program's clinical leader occur.

Also upon implementation, the UNOS will monitor any previously approved islet transplant program that has not been approved or that has opted out of applying for approval under the proposed Bylaws to verify that the program is complying with patient notification and transition plan requirements specified in *OPTN Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

Monitoring of the transition plans will include:

- Reviewing the written notice sent to islet candidates and potential islet candidates
- Reviewing routine reports documenting the program's progress in transferring islet candidates and potential islet candidates to approved islet transplant programs

UNOS will refer a transplant program to the MPSC for further review if the program fails to:

- Notify its islet candidates and potential islet candidates in the time and manner required, if the program is voluntarily inactivating or withdrawing according to *OPTN Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*
- Submit required information to UNOS in the time and manner required

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Committee will monitor the following pre vs. post implementation to assess the impact of proposed changes and whether the changes resulted in an increase in islet programs and islet transplants:

1. The number of islet program applications – including the number approved and declined
2. The number of islet transplants.

Evaluation will be performed at 6 months and 1 year post implementation.

# Policy or Bylaws Language

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

**RESOLVED**, that the creation of **Bylaw Appendix K: Membership and Personnel Requirements for Islet Programs**, as well as changes to **Bylaws Appendices D.6 (Transplant Program Director); D.7 (Transplant Program Key Personnel); D.7.A (Primary Transplant Surgeon and Physician); D.8 (Changes in Key Transplant Program Personnel); D.11 (Review of Transplant Program Functional Inactivity), D.12 (Additional Transplant Program Requirements), G (Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs); G.4 (Requirements for Designated Pancreatic Islet Transplant Programs); G.5 (Primary Pancreatic Islet Transplant Surgeon Requirements); G.6 (Primary Pancreatic Islet Transplant Physician Requirements); K.1 (Transplant Program Inactivity)**, as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

## **Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs**

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

### **D.6 Transplant Program Director**

Each transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program director, along with ~~the primary surgeon and physician program key personnel~~, has the responsibility to submit a detailed Program Coverage Plan (PCP) to the OPTN Contractor ~~that describes how continuous medical and surgical coverage is provided by transplant surgeons and physicians~~. See ~~D.7.BD.8.A: Surgeon and Physician Coverage (Program Coverage Plan)~~ in this appendix and Appendix K.1.A: Islet Transplant Program Clinical Leader Coverage (Program Coverage Plan) for more information on the Program Coverage Plan.

### **D.7 Transplant Program Key Personnel**

Designated transplant programs must have certain key personnel on site according to Table D-1 below.

**D-1: Key Personnel Requirements for Designated Transplant Programs**

<b><u>Designated transplant program type:</u></b>	<b><u>Required key personnel:</u></b>
<u>Kidney, liver, heart, lung, pancreas, or vascularized composite allograft (VCA)</u>	<u>Primary surgeon and primary physician</u>
<u>Islet</u>	<u>Clinical leader</u>

~~These key personnel include a qualified primary surgeon and primary physician that meet the requirements set forth in these Bylaws.~~ For the detailed primary surgeon, and primary physician, or clinical leader requirements for specific organs transplant programs, see the following appendices of these Bylaws:

- *Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs*
- *Appendix F: Membership and Personnel Requirements for Liver Transplant Programs*

- 31 ■ *Appendix G: Membership and Personnel Requirements for Pancreas ~~and Pancreatic Islet~~ Transplant*
- 32 *Programs*
- 33 ■ *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- 34 ■ *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*
- 35 ■ *Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft (VCA)*
- 36 *Transplant Programs*
- 37 ■ *Appendix K: Membership and Personnel Requirements for Islet Transplant Programs*

### 38

### 39 **A.D.8 Primary Transplant Surgeon and Physician**

40 Section D.8: Primary Transplant Surgeon and Physician does not apply to islet transplant programs. See

41 Appendix K.1: Program Director and Clinical Leader.

42

43 The primary surgeon and primary physician are responsible for ensuring the operation and compliance of

44 the program according to the requirements set forth in these Bylaws. The transplant hospital must notify

45 the OPTN Contractor immediately if at any time the program does not meet these requirements. The

46 individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician

47 should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

48

49 A transplant hospital applying as a new member or for a key personnel change must include for the

50 proposed primary surgeon or physician a report from the hospital credentialing committee that the

51 committee has reviewed the individual's state licensing, board certification, and training and confirm that

52 they are currently a member in good standing.

53

54 As part of the plan for continuing policy compliance that is required in the membership application, each

55 primary surgeon or primary physician will submit an assessment of all physicians and surgeons in the

56 program. This assessment must include any involvement in prior transgressions of OPTN obligations and

57 plans to ensure compliance. This information is subject to medical peer review confidentiality

58 requirements and must be submitted according to the guidelines provided in the application and to the

59 satisfaction of the Membership and Professional Standards Committee (MPSC).

### 60

### 61 **D.9 Changes in Key Transplant Program Personnel**

62 Designated transplant programs must have key personnel, ~~specifically a primary surgeon and a primary~~

63 ~~physician,~~ who meet the required minimum levels of commitment to and knowledge of organ procurement

64 and transplantation as specified in these Bylaws. All transplant programs should develop a succession

65 plan that addresses changes in these key personnel.

66

67 When a designated transplant program is informed of a change in key personnel, it must notify the OPTN

68 Contractor within seven business days in writing and follow the procedures that are described below. A

69 change in key personnel can be *any* of the following:

- 70
- 71 ■ Departure of the primary surgeon, ~~or~~ primary physician, or clinical leader.
- 72 ■ Change in position from primary surgeon, ~~or~~ primary physician or clinical leader to an additional
- 73 surgeon or physician.
- 74 ■ Temporary leave.
- 75 ■ Reinstatement of the previously designated primary surgeon, ~~or~~ physician, or clinical leader.

76

77 Transplant programs are also responsible for maintaining Program Coverage Plans ~~as described in~~

78 according to Sections D.7, D.8.A and K.2.A **Error! Reference source not found.** ~~above~~ during changes

79 in key personnel. The Program Coverage Plan must address instances when key personnel are

80 unavailable to perform their transplant duties for short periods of time.

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**A. ~~Primary Surgeon or Primary Physician~~ Key Personnel Departure**

When the transplant hospital is informed that either the primary surgeon, ~~or primary physician, or clinical leader~~ plans to leave the hospital or otherwise end their active participation in the transplant program, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment. The Personnel Change Application must document that the new primary surgeon, ~~or primary physician, or clinical leader~~ meets the requirements of these Bylaws.

If the transplant hospital receives less than 60 days advance notice of the key personnel change, then the transplant hospital must submit a completed Personnel Change Application to the OPTN Contractor within 30 days from the date the OPTN Contractor was notified.

If a program is unable to demonstrate through a completed Personnel Change Application that it has on site ~~both a transplant surgeon and a transplant physician~~ the required key personnel, ~~who meet the requirements for primary surgeon and primary physician~~, the transplant hospital must *either*:

- Inactivate the designated transplant program.
- Withdraw its designated transplant program status ~~as described in~~ according to Section K.4L.4: Withdrawal or Termination of Designated Transplant Program Status of these Bylaws.

**B. ~~Primary Surgeon or Primary Physician~~ Key Personnel Change in Role**

When the transplant hospital plans to propose a new primary surgeon, ~~or primary physician, or clinical leader~~ and the currently designated primary surgeon, ~~or physician or clinical leader~~ will remain on staff as an additional surgeon or physician, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the change will take effect. The Personnel Change Application must document that the new primary surgeon, ~~or physician or clinical leader~~ meets the requirements of these Bylaws.

The transition to the new primary surgeon, ~~or primary physician, or clinical leader~~ is effective after the application has been reviewed and approved by the MPSC or an Ad hoc Subcommittee of the MPSC, ~~as described in~~ according to Appendix A: Membership Application and Review of these Bylaws.

**C. ~~Primary Surgeon or Primary Physician~~ Key Personnel Temporary Leave**

If the primary surgeon, ~~or physician, or clinical leader~~ must take a temporary leave of absence or otherwise temporarily cease their active participation with the transplant program, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the individual's leave begins. The Personnel Change Application must document

132 that the replacement primary surgeon, ~~or~~ physician, or clinical leader meets the requirements  
133 of these Bylaws.

134  
135 Temporary leave is defined in these Bylaws as greater than 30 days but less than one year.  
136

137 If the transplant hospital receives less than 60 days advance notice of the leave, then the  
138 transplant hospital must submit a complete Personnel Change Application to the OPTN  
139 Contractor within 30 days from the date the OPTN Contractor was notified.  
140

141 If a program is unable to demonstrate through a completed Personnel Change Application that it  
142 has on site ~~both a transplant surgeon and a transplant physician~~ the required key personnel who  
143 ~~meet the requirements for primary surgeon and physician~~, the transplant hospital must *either*:  
144

- 145 ■ Inactivate the designated transplant program.
- 146 ■ Withdraw its designated transplant program status ~~as described in~~ according to Appendix KL:  
147 of these Bylaws.

148  
149 **D. Reinstatement of Previously Designated Primary Surgeon or Primary**  
150 **Physician Key Personnel**

151 If the previously designated primary surgeon, ~~or~~ primary physician, or clinical leader returns to the  
152 same transplant program within one year of departure the individual can be considered for  
153 reinstatement ~~as the primary surgeon or primary physician~~. The transplant hospital must submit a  
154 written reinstatement request to the OPTN Contractor.  
155

156 The written reinstatement request must include *all* of the following:  
157

- 158 1. A letter from the Transplant program director, department chair, or chief of the division,  
159 verifying the individual's current working knowledge and experience.
- 160 2. A letter from the individual confirming the individual's on-site availability and commitment to  
161 the program.
- 162 3. A current letter from the hospital credentialing committee verifying that the individual meets  
163 the requirements and is qualified and able to resume as primary surgeon, ~~or~~ primary  
164 physician, or clinical leader.

165  
166 The MPSC or an Ad hoc Subcommittee of the MPSC will review requests for reinstatement, as  
167 described below. In cases where reinstatement of a surgeon, ~~or~~ physician, or clinical leader  
168 affects the transplant program's current status, the MPSC will recommend the appropriate new  
169 program status, along with any resulting special conditions.  
170

171 **E. Failure to Notify the OPTN Contractor of Key Personnel Changes**

172 A member's failure to notify the OPTN of a primary surgeon, ~~or~~ physician, or clinical leader  
173 change or to submit the required Personnel Change Application within the periods specified will  
174 be considered a noncompliance with OPTN Obligations that may result in an OPTN action  
175 according to Appendix LM: Reviews and Actions.  
176  
177

178 **D.4412 Review of Transplant Program Functional Activity**

179  
180 **A. Functional Inactivity**

181 Each transplant program must remain functionally active by performing a minimum number of

182 transplants. For purposes of these Bylaws, functional inactivity is defined as the failure to perform  
 183 a transplant during the periods defined according to Table D-4 2 below.  
 184  
 185

**Table D-4<sub>2</sub>: Functional Inactivity Periods**

<b>Program Type</b>	<b>Inactive Period</b>
<i>Kidney, Liver or Heart</i>	<i>3 consecutive months</i>
<i>Pancreas or Lung</i>	<i>6 consecutive months</i>
<i>Stand-alone pediatric transplant programs</i>	<i>12 consecutive months</i>

186  
 187 Functional inactivity thresholds have not been established for pancreatic islet, intestinal, and VCA  
 188 transplant programs.  
 189

190 **D.4213 Additional Transplant Program Requirements**

191 **A. Transplant Program Performance**

192 ~~Appendix D.12.A does not apply to VCA transplants.~~

193  
 194 The MPSC will conduct reviews of transplant program performance to identify underperforming  
 195 transplant programs and require the implementation of quality assessment and performance  
 196 improvement measures. One measure of transplant program performance is triggered through a  
 197 review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics  
 198 produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to  
 199 identify transplant programs that have lower than expected outcomes.  
 200

201 For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a  
 202 transplant program if it has a higher hazard ratio of mortality or graft failure than would be  
 203 expected for that transplant program. The criteria used to identify programs with a hazard ratio  
 204 that is higher than expected will include *either* of the following:  
 205

- 206 1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
- 207 2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

208  
 209 For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a  
 210 transplant program if the program has one or more events in a 2.5 year cohort.  
 211

212 The MPSC review will be to determine if the higher hazard ratio or events can be explained by  
 213 patient mix or some other unique clinical aspect of the transplant program. If a program's  
 214 performance cannot be explained by patient mix or some other unique clinical aspect of the  
 215 transplant program, the program, in cooperation with the MPSC, will adopt and promptly  
 216 implement a plan for quality improvement. The member's failure to adopt and promptly implement  
 217 a plan for quality improvement will be considered a noncompliance with OPTN Obligations and  
 218 may result in an OPTN action according to *Appendix LM: Reviews and Actions*.  
 219

220 As part of this process, the MPSC may conduct a peer visit to the program at the member's  
 221 expense. The MPSC may also require, at its discretion, that the member participate in an informal  
 222 discussion. The informal discussion will be conducted according to *Appendix LM: Reviews and*  
 223 *Actions*.  
 224

225 The MPSC may recommend that a member inactivate a program, or a component of a program,  
 226 or withdraw its designated transplant program status based on patient safety concerns arising  
 227 from review of the program's graft and patient survival. The MPSC must offer the member an  
 228 informal discussion before recommending that the program inactivate or withdraw its designated  
 229 transplant program status. A program's failure to inactivate or withdraw its designated transplant  
 230 program status when the MPSC recommends it do so will be considered a noncompliance with

231 OPTN Obligations and may result in an OPTN action according to *Appendix LM: Reviews and*  
232 *Actions.*  
233

234 **Appendix G:**  
235 **Membership and Personnel Requirements for**  
236 **Pancreas and Pancreatic Islet Transplant Programs**

237  
238 This appendix describes the information and documentation transplant hospitals are required to provide  
239 when:

- 240 ■ Submitting a completed membership application for approval as a designated pancreas ~~or pancreatic~~  
241 ~~islet~~-transplant program.
- 242 ■ Completing a Personnel Change Application for a change in key personnel at a designated pancreas  
243 ~~or pancreatic islet~~-transplant program.

244  
245 It does not include the general membership requirements that all transplant programs must meet, which  
246 are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant*  
247 *Programs* of these Bylaws.

248  
249 For more information on the application and review process, see *Appendix A: Membership Application*  
250 *and Review* of these Bylaws.

251  
252 **G.4—Requirements for Designated Pancreatic Islet Transplant Programs**

253 All pancreatic islet transplant programs must meet the following criteria:

- 254  
255 1. ~~All of the requirements of a designated pancreas transplant program as defined in the sections above~~  
256 ~~or meet the criteria for an exception as detailed in Section G.4.D: Programs Not Located at an~~  
257 ~~Approved Pancreas Transplant Program below.~~
- 258 2. ~~Demonstrate that the required resources and facilities are available as described in the sections that~~  
259 ~~follow.~~

260  
261 **A.—Transplant Facilities**

262 The program must document adequate clinical and laboratory facilities for pancreatic islet  
263 transplantation as defined by current Food and Drug Administration (FDA) regulations. The  
264 program must also document that the required Investigational New Drug (IND) application is in  
265 effect as required by the FDA.

266  
267 **B.—Expert Medical Personnel**

268 The program must have a collaborative relationship with a physician qualified to perform portal  
269 vein cannulation under direction of the transplant surgeon. It is further recommended that the  
270 program have on site or adequate access to:

- 271  
272 1. ~~A board-certified endocrinologist~~
- 273 2. ~~A physician, administrator, or technician with experience in compliance with FDA regulations~~
- 274 3. ~~A laboratory-based researcher with experience in pancreatic islet isolation and~~  
275 ~~transplantation~~

276  
277 Adequate access is defined as having an agreement with another institution for access to  
278 employees with the expertise described above.

279  
280 **C.—Islet Isolation**

281 Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with  
282 documented collaboration between the program and the facility.  
283

284 **D. ~~Programs Not Located at an Approved Pancreas Transplant Program~~**

285 A program that meets all requirements for a designated pancreatic islet transplant program but is  
286 not located at a hospital approved as a designated pancreas transplant program may qualify as a  
287 pancreatic islet transplant program if the following additional criteria are met:  
288

- 289 1. ~~The program demonstrates a documented affiliation with a designated pancreas transplant~~  
290 ~~program, including on-site admitting privileges for the primary pancreas transplant surgeon~~  
291 ~~and physician.~~
- 292 2. ~~The program provides protocols documenting its commitment and ability to counsel patients~~  
293 ~~about all their options for the medical treatment of diabetes.~~
- 294 3. ~~The program demonstrates availability of qualified personnel to address pre-, peri-, and post-~~  
295 ~~operative care issues regardless of the treatment option ultimately selected. An informal~~  
296 ~~discussion with the MPSC is also required.~~

297  
298 **G.5 ~~Primary Pancreatic Islet Transplant Surgeon Requirements~~**

299 The program must have on site a qualified surgeon who is designated as the primary pancreatic islet  
300 transplant surgeon and meets the requirements for pancreas transplant surgeon defined in these Bylaws.  
301

302 **G.6 ~~Primary Pancreatic Islet Transplant Physician Requirements~~**

303 The program must have on site a qualified physician who is designated as the primary pancreatic islet  
304 transplant physician and meets the requirements for pancreas transplant physician defined in these  
305 Bylaws.  
306

307 **Appendix K:**  
308 **Membership and Personnel Requirements for Islet**  
309 **Transplant Programs**

310 This appendix describes the information and documentation transplant hospitals are required to provide  
311 when:

- 312 ■ Submitting a completed membership application for approval as a designated islet transplant  
313 program.
- 314 ■ Completing a Personnel Change Application for a change in key personnel at a designated islet  
315 transplant program.

316  
317 Transplant programs must also meet certain general membership requirements, which are described in  
318 Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs of these  
319 Bylaws.

320  
321 For more information on the application and review process, see Appendix D: Membership Requirements  
322 for Transplant Hospitals and Transplant Programs of these Bylaws.

323  
324 **K.1 Program Director and Clinical Leader**

325 An islet transplant program must identify at least one designated staff member to act as the transplant  
326 program director. The director must be a physician or surgeon who is a member of the transplant hospital  
327 staff.

328  
329 The program must also identify a qualified clinical leader as described below. The clinical leader is  
330 responsible for ensuring the operation and compliance of the program according to the requirements set  
331 forth in these Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time  
332 the program does not meet these requirements.

333  
334 As part of the plan for continuing policy compliance that is required in the membership application, each  
335 clinical leader will submit an assessment of all physicians and surgeons in the program. This assessment  
336 must include any involvement in prior transgressions of OPTN obligations and plans to ensure  
337 compliance. This information is subject to medical peer review confidentiality requirements and must be  
338 submitted according to the guidelines provided in the application and to the satisfaction of the  
339 Membership and Professional Standards Committee (MPSC).

340 **A. Islet Transplant Program Clinical Leader Coverage (Program Coverage**  
341 **Plan)**

342 The program director, in conjunction with the clinical leader, must submit a detailed Program  
343 Coverage Plan to the OPTN Contractor. The Program Coverage Plan must describe how  
344 continuous medical and surgical coverage is provided by the clinical leader, expert medical  
345 personnel and additional clinicians who have been credentialed by the transplant hospital to  
346 provide transplant services to the program.

347  
348 An islet transplant program must inform its patients if the level of program staffing may create  
349 instances where potential unavailability of certain staff could affect patient care, including the  
350 ability to accept organ offers, procurement, and transplantation.

351  
352 The Program Coverage Plan must address all the following requirements:  
353

- 354           1. Islet transplant programs must have personnel available 365 days a year, 24 hours a day, 7  
355           days a week to provide program coverage, unless a written explanation is provided that  
356           justifies the current level of coverage to the satisfaction of the MPSC.  
357           2. Islet transplant programs must provide patients with a written summary of the Program  
358           Coverage Plan when placed on the waiting list and when there are any substantial changes  
359           in the program or its personnel.  
360           3. An islet clinical leader or additional clinician must be readily available in a timely manner to  
361           facilitate organ acceptance, procurement, and transplantation.  
362           4. Unless the MPSC provides an exemption for specific reasons, the clinical leader cannot be  
363           designated as the clinical leader at more than one islet transplant hospital unless there are  
364           additional clinicians at each of those facilities.  
365           5. Additional clinicians must be credentialed by the transplant hospital to provide islet transplant  
366           services and be able to independently manage the care of islet transplant patients.  
367

## 368 **K.2 Islet Transplant Program Clinical Leader Requirements**

369 The program must identify a surgeon or physician who serves as the clinical leader of the islet transplant  
370 program. The clinical leader of the program, along with the program director, must submit a detailed  
371 Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage  
372 Plan, see Section K.1.A: Islet Transplant Program Clinical Leader Coverage (Program Coverage Plan) of  
373 these Bylaws.  
374

375 The islet transplant program clinical leader must meet all the following requirements:  
376

- 377           1. Have an M.D., D.O., or equivalent degree from another country, with a current license to practice  
378           medicine in the hospital's state or jurisdiction.  
379           2. Be accepted onto the hospital's medical staff, and be on site at this hospital.  
380           3. Have documentation from the hospital credentialing committee that it has verified the clinical leader's  
381           state license, board certification, training, and transplant continuing medical education, and that the  
382           clinical leader is currently a member in good standing of the hospital's medical staff.  
383           4. Have demonstrated direct involvement in the management and care of at least 6 islet transplant  
384           patients, which cumulatively includes selecting donors, evaluating islets, accessing the portal vein for  
385           islet transplant procedures, overseeing the islet infusion and managing immunosuppression. Of the 6  
386           islet transplant patients, at least one must be an allogeneic islet transplant patient. The management  
387           and care of at least one islet transplant patient must have occurred in the last two years. The  
388           management and care of these islet transplant patients must be documented in a log that includes  
389           the date of the care provided, the category of care provided as described above, whether the patient  
390           was an autologous or allogeneic islet transplant patient, and the patient's medical record number or  
391           other unique identifier. This log should be signed by the program director, division chief, or  
392           department chair from the program where the experience was gained.  
393           5. Observe or perform at least three islet isolations, of which at least one must be an allogeneic islet  
394           isolation. These islet isolations must be documented in a log that includes the date of the isolation  
395           procedure, whether the isolation was observed or performed, whether the isolation was for an  
396           autologous or an allogeneic islet transplant and the patient's medical record number or other unique  
397           identifier for autologous transplant use or donor ID for allogeneic transplant use. This log should be  
398           signed by the program director, division chief, or department chair from the program where the  
399           isolations were observed or performed.  
400           6. Have a background in transplantation medicine, immunosuppression management, beta cell biology,  
401           or endocrinology. This background must be demonstrated in documentation submitted to the OPTN

402 contractor of a clinical fellowship lasting at least 6 months in transplantation medicine, transplantation  
403 surgery, immunosuppression management, beta cell biology, or endocrinology.

- 404 7. The following letters must be submitted directly to the OPTN Contractor:
- 405 a. A letter from the director or Chair of the islet program or the director or Chair of another islet  
406 transplant program where the physician or surgeon has served outlining the proposed clinical  
407 leader's overall qualifications to act as islet transplant program clinical leader as well as the  
408 individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN  
409 obligations, and any other matters judged appropriate. The MPSC may request similar letters  
410 of recommendation from others affiliated with any islet transplant program previously served  
411 by the individual, at its discretion.
  - 412 b. A letter from the proposed clinical leader that details the training and experience the  
413 individual has gained in islet transplantation.

414 **A. Board Certification Requirements for a Surgeon Serving as the Clinical**  
415 **Leader**  
416

417 If the clinical leader is a surgeon, the surgeon must have current certification by the American Board  
418 of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal  
419 College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed  
420 training and whose American Board of Urology certification is pending, the Membership and  
421 Professional Standards Committee (MPSC) may grant conditional approval for 16 months to allow  
422 time for the surgeon to complete board certification, with the possibility of one additional 16-month  
423 extension.

424  
425 In place of current certification by the American Board of Surgery, the American Board of Urology, the  
426 American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,  
427 or pending certification by the American Board of Urology, the surgeon must:

- 428 a. Be ineligible for American board certification.
- 429 b. Provide a plan for continuing education that is comparable to American board maintenance of  
430 certification. This plan must at least require that the surgeon obtains 60 hours of Category I  
431 continuing medical education (CME) credits with self-assessment that are relevant to the  
432 individual's practice every three years. Self-assessment is defined as a written or electronic  
433 question-and-answer exercise that assesses understanding of the material in the CME program.  
434 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve  
435 an acceptable self-assessment score are allowed. The transplant hospital must document  
436 completion of this continuing education.
- 437 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated  
438 transplant programs not employed by the applying hospital. These letters must address:
  - 439 i. Why an exception is reasonable.
  - 440 ii. The surgeon's overall qualifications to act as clinical leader of the islet transplant program.
  - 441 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to  
442 OPTN obligations and compliance protocols.
  - 443 iv. Any other matters judged appropriate.

444  
445 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained  
446 the necessary CME credits with self-assessment, the transplant program will have a six month grace  
447 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six  
448 month grace period, and a key personnel change application has not been submitted, then the  
449 transplant program will be referred to the MPSC for appropriate action according to Appendix M of  
450 these Bylaws. If the OPTN Contractor becomes aware that a clinical leader has not been compliant  
451 for 12 months or more and deficiencies still exist, then the transplant program will not be given any  
452 grace period and will be referred to the MPSC for appropriate action according to Appendix M of  
453 these Bylaws.

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**B. Board Certification Requirements for a Physician serving as the Clinical Leader**

457 If the clinical leader is a physician with a background in transplantation medicine, immunosuppression  
458 management, beta cell biology, or endocrinology, the physician must have current board certification  
459 in nephrology, endocrinology, immunology, or diabetology by the American Board of Internal  
460 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of  
461 Canada.

462  
463 In place of current certification in nephrology, endocrinology, immunology, or diabetology by the  
464 American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of  
465 Physicians and Surgeons of Canada, the physician must:

- 466 a. Be ineligible for American board certification.
- 467 b. Provide a plan for continuing education that is comparable to American board maintenance of  
468 certification. This plan must at least require that the physician obtains 60 hours of Category I  
469 continuing medical education (CME) credits with self-assessment that are relevant to the  
470 individual's practice every three years. Self-assessment is defined as a written or electronic  
471 question-and-answer exercise that assesses understanding of the material in the CME program.  
472 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve  
473 an acceptable self-assessment score are allowed. The transplant hospital must document  
474 completion of this continuing education.
- 475 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated  
476 transplant programs not employed by the applying hospital. These letters must address:
  - 477 i. Why an exception is reasonable.
  - 478 ii. The physician's overall qualifications to act as a clinical leader of an islet transplant program.
  - 479 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to  
480 OPTN obligations and compliance protocols.
  - 481 iv. Any other matters judged appropriate.

482 If the physician has not adhered to the plan for maintaining continuing education or has not obtained  
483 the necessary CME credits with self-assessment, the transplant program will have a six month grace  
484 period to address these deficiencies. If the physician has not fulfilled the requirements after the six  
485 month grace period, and a key personnel change application has not been submitted, then the  
486 transplant program will be referred to the MPSC for appropriate action according to Appendix M of  
487 these Bylaws. If the OPTN Contractor becomes aware that a physician clinical leader has not been  
488 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be  
489 given any grace period and will be referred to the MPSC for appropriate action according to Appendix  
490 M of these Bylaws.

491 **K.3 Additional Requirements for Designated Islet Transplant Programs**

492 All islet transplant programs must demonstrate that the required resources and facilities are available as  
493 described in the sections that follow.

494  
495

**A. Transplant Facilities**

496 The program must document adequate clinical and laboratory facilities for islet transplantation as  
497 defined by current Food and Drug Administration (FDA) regulations. The program must also  
498 document that the required Investigational New Drug (IND) application or approved Biologics  
499 License Application (BLA) is in effect as required by the FDA.

500  
501

**B. Expert Medical Personnel**

502 The program must have on site:  
503

- 504           1. An abdominal surgeon  
505           2. A surgeon or interventional radiologist who has performed at least three portal vein access  
506           procedures  
507           3. A physician to handle immunosuppression who has managed at least six  
508           immunosuppression management cases  
509           4. An endocrinologist or physician who is experienced in metabolic studies

510  
511           Any individual, including the clinical leader, may fill one or more of the expert medical personnel  
512           positions.  
513

514           **C. Additional Medical Personnel**

515           The program must have on site, or adequate access, to:

- 516  
517           1. A person with experience in compliance with FDA regulations  
518           2. A diabetes educator  
519           3. A scientist with experience in islet quality assessment

520           Adequate access is defined as having an agreement with another institution for access to  
521           employees with the expertise described above.  
522

523           **D. Islet Isolation**

524           Islets must be isolated in a facility with an FDA IND or approved BLA application in effect, with  
525           documented collaboration between the program and the facility.  
526  
527

528 **Appendix ~~K~~L:**

529 **Transplant Program Inactivity, Withdrawal, and**  
530 **Termination**

531 This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what  
532 members must do to be in compliance with OPTN obligations during these periods.

533

534 **~~K~~L.1 Transplant Program Inactivity**

535 Transplant programs must remain active in transplantation to maintain membership in the OPTN. There  
536 are two types of member inactivity:

537

538 1. Short-term Inactivity

539 2. Long-term Inactivity

540

541 A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons  
542 including but not limited to:

543 ■ The inability to meet functional activity requirements.

544 ■ The inability to serve potential candidates, candidates, recipients, potential living donors, or living  
545 donors for a period of 15 or more consecutive days.

546 ■ Temporarily lacking required ~~physician or surgeon~~ key personnel coverage.

547 ■ A substantial change in operations that requires an interruption in transplantation.

548 For more information about the functional activity requirements for transplant programs, see *Section*  
549 *D.4.12: Review of Transplant Program Functional Activity* of these Bylaws.

550

551 [Subsequent heading numbers, and any table captions and cross-references, affected by the re-  
552 numbering of these bylaws will also be changed as necessary.]

553

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## RESOLUTION 1

**RESOLVED**, that the creation of Bylaw Appendix K: Membership and Personnel Requirements for Islet Programs, as well as changes to Bylaws Appendices D.6 (Transplant Program Director); D.7 (Transplant Program Key Personnel); D.7.A (Primary Transplant Surgeon and Physician); D.8 (Changes in Key Transplant Program Personnel); D.11 (Review of Transplant Program Functional Inactivity), D.12 (Additional Transplant Program Requirements), G (Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs); G.4 (Requirements for Designated Pancreatic Islet Transplant Programs); G.5 (Primary Pancreatic Islet Transplant Surgeon Requirements); G.6 (Primary Pancreatic Islet Transplant Physician Requirements); K.1 (Transplant Program Inactivity), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.