At-a-Glance

Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion

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- **Affected Policies and Bylaws:** Policy 3.8.7.2 (Accrual of Waiting Time); Policy 3.8.7.4 (Process for Re-Allocating Islets); Policy 3.8.7.5 (Removal from the Pancreas Islet Waiting List); Section G.4 (Requirements for Designated Pancreatic Islet Transplant Programs) in Appendix G of the OPTN Bylaws; and, Section 1.2.D (Registration Fees) in Article I of the OPTN Bylaws

- **Pancreas Transplantation Committee**

- The goal of this proposal is to require the accurate and timely reporting of every islet infusion to the OPTN Contractor and to update language in policies and bylaws to reflect current practice for reporting islet infusions and outcomes information. Currently, islet Transplant Programs are not required to report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have implications for patient safety or disease transmission. This proposal:

  1. Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
  2. Removes outdated requirements in the bylaws for submitting islet logs.
  3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed from the waiting list for transplant and immediately re-registered for another infusion.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients

- **Number of Potential Candidates Affected**
  In 2011, there were approximately 70 islet recipients. Islet recipients benefit from an accurate and timely reporting of each islet infusion because it allows for more efficient notification of patient safety or disease transmission events.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal addresses the OPTN Strategic Plan goal to promote transplant patient safety. By having accurate and timely reporting of every islet infusion, it will be easier for both Members and the OPTN Contractor's patient safety and disease transmission staff to notify the islet

program and recipient of any potential patient safety or disease transmission events. This proposal also addresses the OPTN Strategic Plan goal to promote the efficient management of the OPTN by aligning the process for reporting islet transplants with the process and timeframes for reporting all other organ transplants.

- **Specific Request for Comment**
  Does this proposal make clear that islet candidates can still accrue waiting time through three islet infusions, even though they must now be removed from the waiting list within 24 hours of each infusion instead of only after the third infusion?

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Pancreas Transplantation Committee

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The goal of this proposal is to require the accurate and timely reporting of every islet infusion to the OPTN Contractor and to update language in policies and bylaws to reflect current practice for reporting islet infusions and outcomes information. Currently, islet Transplant Programs are not required to report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have implications for patient safety or disease transmission. This proposal:

1. Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
2. Removes outdated requirements in the bylaws for submitting islet logs.
3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed from the waiting list for transplant and immediately re-registered for another infusion

Background and Significance of the Proposal:

Currently, islet policy allows an islet candidate to retain waiting time through three infusions. The islet Transplant Program has to remove the candidate from the waiting list only after the third islet infusion. The bylaws require that each transplant hospital submit islet logs accounting for every pancreas accepted for islets at the hospital, but those logs have never been collected. As a result, the OPTN Contractor does not have an official avenue for tracking every islet infusion.

The UNet℠[1] system already contains a process for removing and automatically re-registering an islet candidate. When a Transplant Program removes a pancreas islet (PI) candidate from the waiting list, the UNet℠ system asks the Transplant Program "Re-List Candidate?" if the number of islet infusions for that candidate's registration is fewer than three. If the transplant hospital selects "Yes" as a response, then the UNet℠ system adds the candidate back to the PI waiting list, retaining the same waiting time the candidate had upon removal. Therefore, the OPTN Contractor already has a programmed solution in the UNet℠ system that would allow an islet Transplant Program to remove a candidate from the PI list after each infusion, but still allow the candidate to retain waiting time through three infusions.

[1] UNet℠ is a network of transplant applications, developed by the OPTN Contractor, that are interconnected to provide for the candidate waiting list, the organ placement process, data collection, and data security.

Currently, when a Transplant Program makes use of this process, the UNet℠ system does not create an additional invoice for the second or third registration. However, when a Transplant Program registers an islet candidate to the waiting list for a second or third infusion, but without using this automatic re-registration functionality, the UNet℠ system creates an additional registration fee. The Pancreas Transplantation Committee (the "Committee") is proposing new bylaws language to reflect the current programming but requests public comment on this automated scenario. The Committee believes that a single registration fee for three infusions is appropriate, because the transplant is not complete until the candidate has received enough islets to become insulin independent, which often requires more than one infusion. Additionally, the cost to change the programming is likely to be far greater than the revenue generated by the additional fees charged for the second and third islet infusions, because islet volume is so small.

The Committee considered the following potential revisions to islet policies and bylaws:

- Require reporting to the OPTN Contractor within 24 hours of every infusion (but still allow waiting time to accrue up to and including three infusions).
- Clarify that each islet registration (as opposed to candidate) can retain waiting time through three islet infusions.
- Remove language in the bylaws about islet logs.
- Add language in the bylaws explaining the current programming that does not create an additional registration fee when an islet candidate is removed for transplant and concurrently re-listed using the process described in the paragraph above.

The Committee agreed that the changes considered would improve the process for tracking islet infusions.

The Committee also considered the impact on patient notification due to registration on and removal from the waiting list. Policy 3.2.8 (Patient Notification) requires that Transplant Hospitals notify patients in writing within 10 business days of the patient's registration on the waiting list. Islet programs would likely need to send a letter every time they added an islet candidate to the waiting list. The Committee thought it appropriate for Transplant Hospitals to inform candidates that they were still on the waiting list and had the potential to receive islet offers. The Committee thought the burden on the islet program to inform candidates that they were still on the waiting list, would be small because of low volume. Furthermore, the Committee did not want to create additional exceptions for islet transplantation. The reason for allowing islet candidates to retain waiting time through three infusions was a clinical one. If islet candidates could receive more than one infusion in close succession, then they may need only one course of induction. These same arguments do not apply to exceptions to administrative processes like patient notification.

In general, this proposal better aligns the process for tracking islet infusions with the processes for tracking other organs. The proposal also is the first step in being able to compare outcomes between islets and whole pancreas transplantation. After the Committee has an accurate count of the number of islet infusions, full reporting of the recipients who received infusions, and which deceased donors donated islets, then the Committee can devise methods for comparing demographic and outcomes data between whole pancreas and islet transplantation.

The Committee considered leaving the islet policies and bylaws as is. The Committee ultimately decided against that approach, because an islet is the only organ that the OPTN Contractor cannot fully track. The Committee believes that if accurate accounting of other organs is important, then the same

arguments would apply for islets. Additionally, the fact that the islet logs were not being collected showed that it was not an effective way for islet data to be collected. Because a method for tracking each islet infusion was already programmed and some islet programs were already reporting each islet infusion using that method, the Committee decided to require that every infusion be reported in the UNet℠ system, which is similar to what is required for every other organ.

In revising the islet policy, the Committee removed reference to Policy 6.4.1 (Exportation) in Policy 3.8.7.4. In June, 2012, the OPTN/UNOS Board of Directors deleted Policy 6.4.1 and on September 1, 2012, the content in Policy 6.4.1 became part of Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members). Policy 3.8.7.4 already references Policy 3.2.1.4.

On July 30, 2012, the Committee voted by telephone in favor of the proposed policy and bylaw changes for submission for public comment: 13-supported; 0-opposed; and, 0-abstained.

Supporting Evidence and Modeling:

On December 31, 2011, there were 217 registrations and 212 candidates on the pancreas islet waiting list. The number of pancreas islet registrations increased from 182 registrations in 1999 to 334 registrations in 2002 and remained relatively stable through 2005. Between 2005 and 2008, however, registrations decreased to 190 and have since increased only slightly. As expected, trends in the number of pancreas islet candidates followed the same pattern as that of registrations, with very few candidates listed at multiple hospitals.

In 2011, there were 61 deceased donor pancreata reported to the OPTN with a disposition code of "Islet Cells Transplanted." There were 87 removals from the waiting list in 2011 for pancreas islet infusions reported to the OPTN. 70 recipients were removed from the waiting list for pancreas islet transplants. The discrepancy in these numbers is caused by the removals for recipients removed more than once; 15 recipients were removed twice and one recipient was removed thrice for pancreas islet transplants. The difference in the number of donors reporting that islet cells were transplanted and the number of recipients removed from the waiting list for an islet cell transplant shows that the OPTN does not have a precise count of the number of islet transplants. However, both numbers show that the number of islet transplants annually is likely less than 100.

As of July, 2012, there are currently 21 approved pancreas islet programs.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

This proposal affects islet recipients because it shows which islet recipients have received islets from deceased donors. This information would be particularly important if an OPO needed to notify recipients of a potential disease transmission or other patient safety issue. There were approximately 60-80 islet infusions in 2011. This proposal would allow the OPTN Contractor to have a more accurate count of the impact of islet policy changes.

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

The proposal addresses the OPTN Strategic Plan goal to promote transplant patient safety. By having accurate and timely reporting of every islet infusion, it will be easier for both members and the OPTN Contractor's patient safety and disease transmission staff to notify the islet program and recipient of any potential patient safety or disease transmission events.

This proposal also addresses the OPTN Strategic Plan Goal of promoting efficient management of the OPTN. First, it aligns the process for reporting islet transplants with the process and timeframes for reporting all other organ transplants. Additionally, this proposal removes outdated language in the bylaws about requiring islet logs. Islet programs cannot comply with those requirements because there is no mechanism for collecting the logs. That situation creates confusion and inefficiencies for both Members and the OPTN Contractor's staff when Transplant Programs try to determine how to comply with OPTN requirements.

Plan for Evaluating the Proposal:

The Committee will review the number of islet transplants annually and compare it to the number of deceased donors when the disposition of the pancreas is "islet cells transplanted." The Committee expects each donor ID with the "islet cells transplanted" disposition code to match to an islet candidate who has been removed from the waiting list with a removal code of "transplanted." Without the requirement to report every islet infusion, that comparison cannot be done.

The Committee asserts that the number of islet donors and islet recipients should be the same. If the numbers are not the same, then this proposed policy and bylaw changes may not have achieved its goal of accurate and timely reporting of every islet infusion. The Committee will then investigate whether there is a policy compliance issue or whether it needs to pursue an alternate solution.

Additional Data Collection:

This proposed policy and bylaw change does not require additional data collection, but does require islet Transplant Programs to report data on islet infusions on a different time frame. Transplant Programs already collect these data, and the Unet℠ system already has an automated mechanism for reporting islet infusions. However, Transplant Programs do not use this automated mechanism consistently.

Expected Implementation Plan:

The Board will consider this proposal in June, 2013. If approved by the Board, the proposed policy and bylaw language will be effective on September 1, 2013. (The proposal will not require programming in UNet℠.)

If approved, islet Transplant Programs must remove islet recipients from the waiting list within 24 hours of each islet infusion instead of 24 hours of the recipient's third islet infusion. Policy 3.2.8 (Patient Notification) requires that Transplant Hospitals notify patients in writing within 10 business days of the patient's registration on the waiting list. If this proposal is a change in practice for the islet program, then the program should review its patient notification protocol to make sure that it is addressing cases when an islet recipient receives an islet transplant and is immediately re-registered for another infusion.

Islet programs no longer will be required to submit cumulative islet logs reporting each islet infusion and outcomes.

Compliance Monitoring:

The proposed policy changes would not affect the OPTN Contractor's monitoring.

Policy and Bylaw Proposal

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

3.8.7 Islet Allocation Protocol

[There are no policy changes preceding Policy 3.8.7.2.]

3.8.7.2 Accrual of Waiting Time~~.~~

A candidate will begin to accrue islet waiting time when the candidate is registered on the waiting list. Candidates accrue waiting time while registered at an active or inactive status.

An islet candidate will retain waiting time through three registrations at the registering center, including the waiting time from the previous registrations and any intervening time. After a candidate has received a series of three islet infusions at the registering hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions,

~~A candidate is eligible to accrue waiting time:~~

- ~~while listed in an active or inactive status; and~~
- ~~until the candidate has received a maximum of three islet infusions.~~

~~Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.~~

[There are no further changes in Policy 3.8.7.2.There are no changes in Policy 3.8.7.3.]

3.8.7.4 Process for Re-Allocating Islets. If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request.
Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,

- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers, and

- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run~~,~~.

- ~~Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.~~

3.8.7.5 Removal from the Pancreas Islet Waiting List~~.~~

The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving each ~~his/her third~~ islet infusion.

G.4 Requirements for Designated Pancreatic Islet Transplant Programs

All Pancreatic Islet Transplant Programs must meet the following criteria:

1. All of the requirements of a Designated Pancreas Transplant Program as defined in the sections above *or* meet the criteria for an exception as detailed in Section *G.4.E: Programs Not Located at an Approved Pancreas Transplant Program* below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

~~A.~~ ~~Reporting~~

~~The Program must submit data to the OPTN Contractor for all donors, potential transplant recipients, and actual transplant recipients using the required forms.~~

~~Pending development of standardized data forms for pancreatic islet transplantation, the Program must maintain patient logs and provide them to the OPTN Contractor every 6 months. The patient logs must be cumulative and must include for each transplant performed:~~

~~1. The patient name~~
~~2. Social security number~~
~~3. Date of birth~~
~~4. Donor ID~~
~~5. Patient status (alive or dead)~~
~~6. Whether the pancreas was allocated for islet or whole organ transplantation~~

~~For each pancreas allocated to the Program for islet transplantation, the Program must report to the OPTN Contractor if the islets were used for transplantation. If the islets were not used in transplantation, the Program must report the reason and disposal method, together with other information requested on the Pancreatic Islet Donor Form.~~

A~~B~~. Transplant Facilities

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

B~~C~~. Expert Medical Personnel

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

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

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

C~~D~~. Islet Isolation

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

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

A Program that meets all requirements for a Designated Pancreatic Islet Transplant Program but is not located at a hospital approved as a Designated Pancreas Transplant Program may qualify as a Pancreatic Islet Transplant Program if the following additional criteria are met:

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

D. Registration Fees

Transplant hospital members are responsible for the payment of an OPTN Registration Fee for each transplant candidate ~~listed~~ registered by that member on the waiting list database maintained by the OPTN Contractor. The OPTN Registration Fee is proposed by the Board of Directors and determined by the Secretary of HHS.

An additional registration fee will be due for a transplant candidate if:

- A candidate is given an inactive status or removed from the waiting list without receiving a transplant and is not placed back on the list within the 90-day grace period.
- A recipient has received a transplant but is put back on the waiting list for another transplant. However, no additional registration fee will be due for an islet candidate who is removed and, if the option to re-register is offered during the removal process, immediately re-registered for an islet infusion.
- A candidate is transferred to a transplant hospital *outside* the original OPO Donation Service Area. A new registration fee must be paid by the receiving hospital.
- The potential recipient is listed at multiple transplant hospitals. A registration fee must be paid by each transplant hospital that places the candidate on the waiting list.

Members who ~~list~~ register candidates needing more than one organ (for example, kidney and pancreas) are only charged one registration fee.