OPTN/UNOS Pancreas Transplantation Committee

Proposal to Revise Facilitated Pancreas Allocation Policy

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Executive Summary 2
Is the sponsoring committee requesting specific feedback or input about the proposal? 2
What problem will this proposal solve? 3
Why should you support this proposal? 3
Which populations are impacted by this Proposal? 8
How does this proposal support the OPTN Strategic Plan? 8
How will the sponsoring committee evaluate whether this proposal was successful post implementation? 9
How will the OPTN implement this proposal? 9
How will members implement this proposal? 9
How will members be evaluated for compliance with this proposal? 10
Policy or Bylaw Language 11

Proposal to Revise Facilitated Pancreas Allocation Policy

Executive Summary

The Pancreas Transplantation Committee offer a proposal that will expedite organ placement by updating the mechanics of facilitated pancreas allocation. Such changes will combat a troubling trend of growing pancreas underutilization rates by shifting facilitated pancreas allocations from a list of volunteer programs to one of programs with a recent record of frequently importing pancreata external to their Donation Service Area (DSA). This proposal calls for the revision of Policy 11.7 by splitting it into two subsections; *Policy 11.7.A: Transplant Program Qualifications* outlines eligibility requirements for programs to participate while *11.7.B: Facilitated Pancreas Offers* explains the process by which an organ procurement organization (OPO) or the Organ Center can use facilitated pancreas allocation. This proposal coincides with the first goal of the Organ Procurement and Transplantation Network's (OPTN) Strategic Plan to increase the number of transplants by offering imported pancreata to those programs most likely to use them.

Is the sponsoring committee requesting specific feedback or input about the proposal?

The key issues of this proposal for the public to consider are:

- Will the qualifying criteria put forth in this proposal improve facilitated pancreas allocation as well as improve pancreas allocation and increase pancreas utilization?
- Will the increased allocation timeframe put forth in this proposal benefit facilitated pancreas allocation thus increasing pancreas transplantation?

These statements and questions are not an exhaustive list and reviewers are encouraged to comment on the entire proposal.

Proposal to Revise Facilitated Pancreas Allocation Policy

Affected Policies: Policy 11.7 Administrative Rules

Sponsoring Committee: Pancreas Transplantation Committee

Public Comment Period: August 14 – October 14

What problem will this proposal solve?

The goal of the pancreas underutilization project is twofold: to uncover the reason(s) for decline in the number of pancreas transplantations and implement strategies to combat this decline. This specific proposal coincides with the latter, addressing known allocation challenges, beginning with revisions to improve facilitated pancreas allocation.[1] Facilitated pancreas allocation is an additional pancreas allocation method that takes effect after a period where the pancreas offer has not been accepted for a candidate or when the time for procurement is shortly approaching. The current facilitated pancreas allocation system only places a small number of pancreata (in 2008, 370 pancreata were offered through facilitated pancreas allocation and 35 pancreata were placed; in 2010, 298 pancreata were offered through facilitated pancreas allocation and 11 pancreata were placed). Relative to the decreasing number of successfully utilized pancreata however, the transplant numbers are significant enough that resources should be dedicated to revising policy to try to increase the number of pancreas transplants. Additionally, this proposal would allow OPOs to use facilitated pancreas allocation, rather than just the Organ Center, which may also increase utilization of facilitated pancreas allocation. Facilitated pancreas allocation is an important alternative allocation method for utilizing organs that are otherwise not accepted and adjustments to facilitated pancreas allocation represent a “first step” in acting to increase pancreas transplants through more effective placement of the organ.

Why should you support this proposal?

The proposed changes establish a system in which facilitated pancreas offers are made to those transplant programs that have a recent record of importing deceased donor pancreas organs for transplant. Any transplant hospital with a designated pancreas transplant program is eligible for the facilitated list if they can meet certain qualifying criteria. Whereas current policy only requires a letter of intent, the proposed changes will require participating programs to perform at least five (5) pancreas transplants using imported pancreata within one of the two previous years prior to the annual review. The list of programs will be recalculated each year to ensure fairness and access to those wishing to participate.

For the transplant programs, the above-mentioned changes incentivize performing a reasonable number of import-organ transplants by granting those programs access to facilitated pancreas allocation. For the waiting list candidates, these changes could result in shorter wait times, while also increasing utilization of an organ readily available, but seldom recovered and implanted successfully.

Additionally, this proposal provides OPOs with the ability to use facilitated pancreas allocation, rather than just the Organ Center. Empowering OPOs with the ability to use facilitated pancreas allocation should increase utilization of pancreata that would otherwise be unused.

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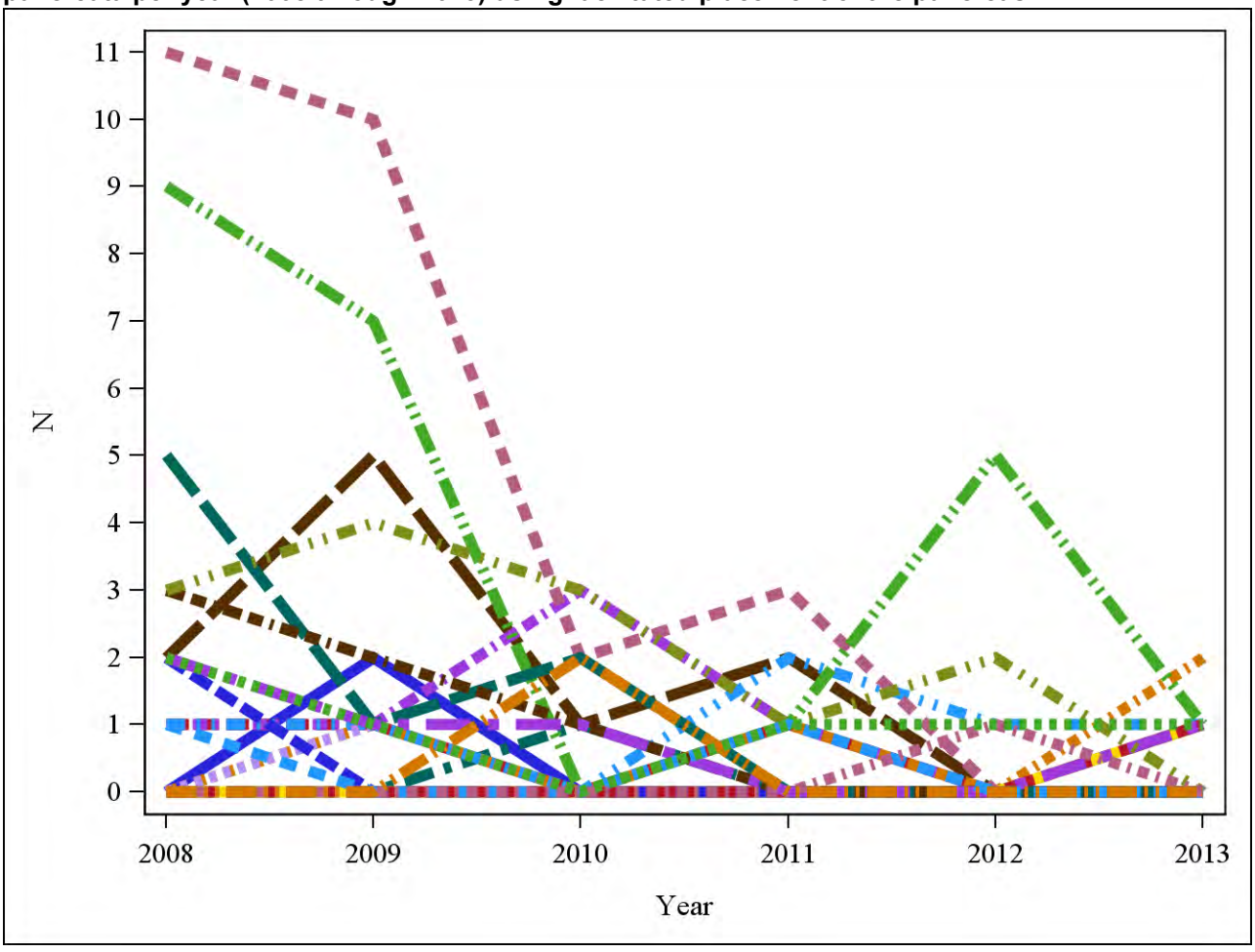
[1] See OPTN/UNOS Policy 11.7.A (Facilitated Pancreas Allocation), available at http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_11.

How was this proposal developed?

The Pancreas Transplantation Committee assessed the current and potential impact of the facilitated pancreas allocation system and proposed changes to the system to strengthen its purpose. The Committee studied data as submitted to the OPTN from 2008 through 2014 to identify trends in pancreas transplantation and more specifically, facilitated pancreas allocation. The Committee determined that the facilitated pancreas allocation system is infrequently used as it is currently constructed, and conjectured that changes to this system could increase pancreas utilization and transplant volumes nationwide.

The data below in Figure 1 shows the number of pancreas transplants per year performed by transplant programs that are currently participating in the facilitated allocation system with the pancreas allocated through the facilitated system. In Figure 1, a different colored line represents each transplant program that is currently on the list to receive facilitated pancreas offers. Each line shows the volume of pancreas transplants performed using a pancreas allocated through facilitated pancreas allocation.

Figure 1. For all programs that are on the facilitated pancreas list, the number of transplanted pancreata per year (2008 through 2013) using facilitated placement of the pancreas.



In 2008, one program performed 11 transplants, one performed nine and another performed five. In 2012, one program performed five transplants and no other program performed more than two pancreas transplants from facilitated allocation. In the last two years, there were only 10 total pancreas transplants performed using facilitated pancreas each year. In 2008, there were 43 transplants performed using facilitated pancreas allocation.

Figure 1 shows that programs that were once very active in using this system do not appear to be maximizing the system anymore, and many of the programs on the facilitated pancreas allocation list have never accepted and transplanted more than three or four pancreata in a year using this allocation method.

The committee understood that programs on the facilitated pancreas allocation list are not widely accepting and transplanting pancreata using this methodology. In response, the Committee asked if the programs on the facilitated pancreas list are importing many pancreata in general for their pancreas transplants. Figure 2 shows the number of simultaneous pancreas-kidney (SPK) and pancreas alone (PA) transplants done by each pancreas transplant program by the percent of their transplants that were performed using organs recovered from outside the transplant program's DSA, defined as an import transplant. No pancreas or kidney-pancreas transplants were excluded from Figure 2. The markers in the plot are colored and shaped by whether or not the program is on the facilitated pancreas allocation list.

Figure 2. For all Deceased Donor Pancreas and Simultaneous Pancreas Kidney (SPK) Transplants in the US from 2008 through 2013, the number of transplants by program by the percent of transplants that were performed using import donors (donors shared regionally or nationally).

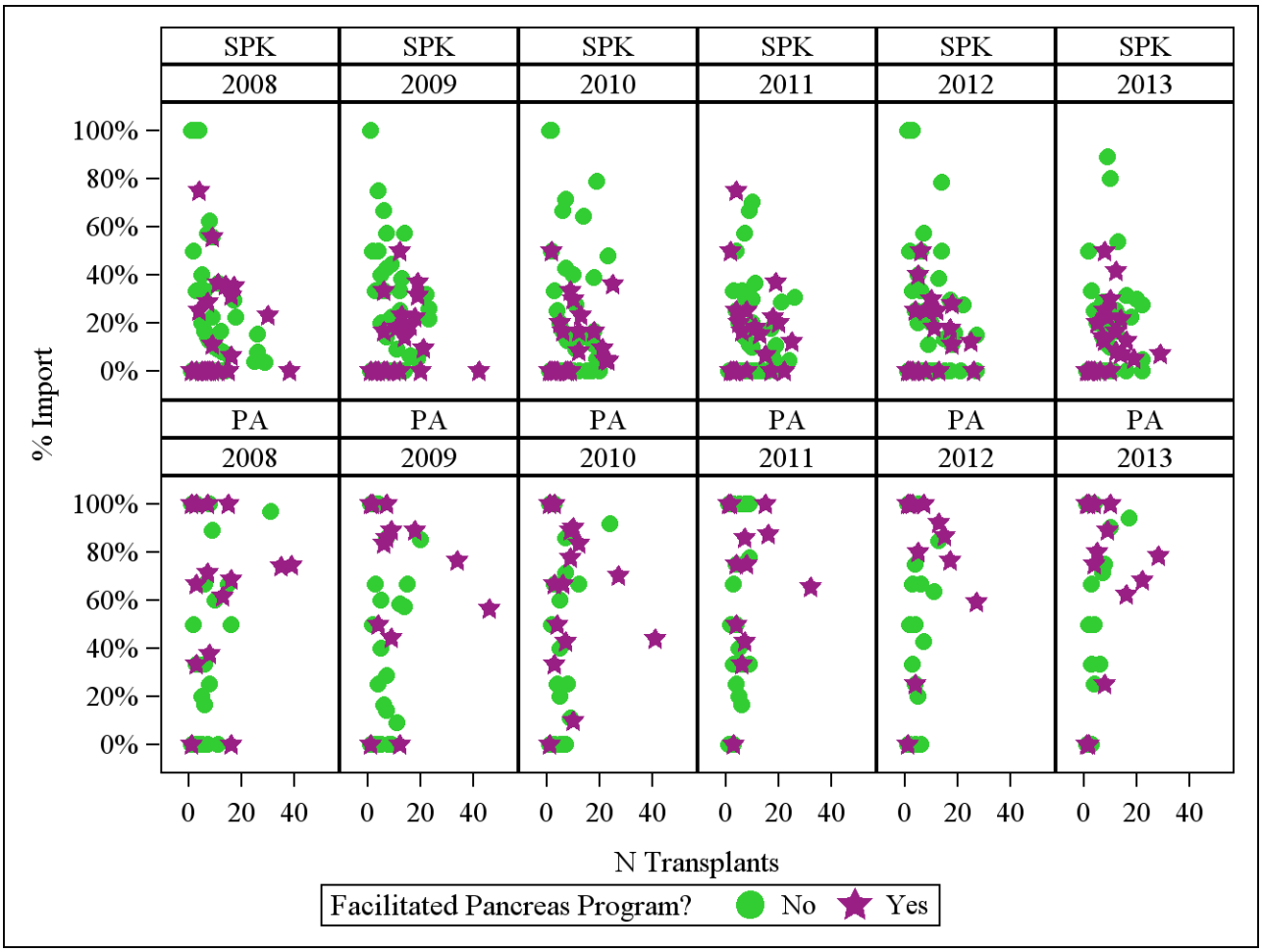


Figure 2 shows that a higher percentage of pancreas alone transplants are performed with imported organs than SPK transplants. It is also seen that of the programs on the facilitated pancreas allocation list, many import a large percentage of their pancreas alone transplants. There are some programs on the list that have not been importing a large percentage of their transplants recently, and some that perform zero import pancreas transplants in a year. Perhaps more relevant to this proposal, there are multiple

programs with a high percentage of import donor transplants that are not on the facilitated allocation list. The Committee opined that programs with a demonstrated history of using imported organs for pancreas transplants should be the programs receiving facilitated offers, rather than the programs that use only local donors for pancreas transplants. Overall, the shapes of these distributions have not changed greatly over time.

The Committee conjectured that if the facilitated pancreas allocation list is comprised of programs with established records of importing and transplanting deceased donor pancreata, then the facilitated pancreas allocation system should increase pancreas utilization and transplantation.

How well does this proposal address the problem statement?

The Committee requested data to assess the potential impact of implementing the criterion for qualification. Specifically, the committee asked if these qualifying criteria would yield a similar number of programs on the list compared to the current list comprised of programs that signed up to participate. The Committee also asked how many programs from the original list that volunteered to participate would qualify. Table 1 shows the number of programs that would be qualified for facilitated pancreas allocation if the proposed policy were implemented. Of the 31 programs currently on the facilitated pancreas allocation list, only 14 of them would have qualified in 2010, 11 in 2011, 12 in 2012 and 2013, and 11 in 2014. No more than three programs per year since 2009 performed a facilitated pancreas transplant and would not qualify with the new rules (N=5 in 2008).

Table 1. Number of programs performing pancreas transplants in the United States from 2008 through 2014 by the number that would qualify under the proposed facilitated pancreas rule from 2010 through 2014.

Year	Facilitated Pancreas Qualified?		Total
	No	Yes	
	N	N	N
2010	113	32	145
2011	117	28	145
2012	117	28	145
2013	118	27	145
2014	122	23	145

These results support that the new policy would change which programs are receiving facilitated pancreas offers, and the Committee proposes that sending these offers to programs with recent evidence of transplanting imported pancreata would increase the increase the number of transplants through increased efficiency of the system. The Committee concluded that implementing the proposed qualifying criteria would yield an appropriate number of programs to receive facilitated pancreas offers and is relatively close to the current volume.

In an attempt to clarify how this system and annual reviews will work, five programs were randomly selected that qualified for at least 1 year and less than all five years from 2010 through 2014 using the proposed policy. The data applicable to qualification is displayed in Table 2.

Table 2. Examples of programs that would not have qualified for all five years from 2010 through 2014 based on their import volume of pancreas and simultaneous pancreas-kidney transplants, and details on when they qualified, and with what volumes.

		Annual Data					
Program (Encrypted)	N Years Qualified from 2010 through 2014	Year	N Total Pancreas Transplants	N Imported TX in Year	N Imported TX in Year 1 Previous	N Imported TX in Year 2 Previous	Qualified?
00248	4	2010	16	11	3	5	Yes
		2011	10	7	11	3	Yes
		2012	0	0	7	11	Yes
		2013	2	0	0	7	Yes
		2014	4	0	0	0	No
12152	3	2010	16	5	2	7	Yes
		2011	6	2	5	2	Yes
		2012	11	3	2	5	Yes
		2013	9	4	3	2	No
		2014	12	2	4	3	No
16523	3	2010	27	5	3	5	Yes
		2011	28	4	5	3	Yes
		2012	32	1	4	5	Yes
		2013	25	2	1	4	No
		2014	24	6	2	1	No
19034	1	2010	15	0	0	0	No
		2011	15	0	0	0	No
		2012	27	4	0	0	No
		2013	23	6	4	0	No
		2014	25	1	6	4	Yes
19747	3	2010	10	2	3	5	Yes
		2011	6	5	2	3	No
		2012	4	1	5	2	Yes
		2013	0	0	1	5	Yes
		2014	1	0	0	1	No

This shows that program behavior in decreasing volumes of pancreas transplants as well as volumes of imported pancreas transplants cause programs to no longer qualify for facilitated allocation. Two transplant programs shown in Table 2, 16523 and 19034, are relatively high volume pancreas transplant programs that have not imported enough of their pancreas transplants to qualify for facilitated pancreas allocation. Programs that perform a high volume of pancreas transplants using only local donors will not qualify based on the proposed rule. For all of these calculations, as well as for proposed implementation of the policy, pancreas alone as well as simultaneous pancreas-kidney transplants are counted towards the qualifying criteria.

Another aspect of this proposed policy change is that OPOs and the Organ Center will have the ability to use facilitated pancreas allocation. Currently, only the Organ Center has access to this functionality. The Committee believes allowing OPOs access to facilitated allocation will increase its utilization. In addition

to this change, the OPO or the Organ Center may now switch to facilitated pancreas allocation within three hours of the donor organ recovery rather than only one hour as policy currently allows. To make sure the timing change would not bias established pancreas allocation, the amount of time spent offering pancreas and kidney-pancreas organs from the combined match run was measured beginning around the implementation of the new pancreas allocation system on October 30, 2014.

From November 1, 2014 through May 31, 2015, all combined pancreas/kidney-pancreas match runs were queried if (a) the first offer was made electronically to the first potential transplant recipient on the match run and (b) the donor cross-clamp date/time was entered. The amount of time between the first offer and the cross-clamp was used as an approximate measure of how long the OPO or Organ Center spent trying to place a pancreas. Overall, the average time from first offer to cross-clamp time was 19.3 hours (SD=10.7). For pancreas organs that were recovered the average was 21.1 (SD=10.7) and for those that were not recovered the average was 18.7 (SD=9.8). For all offers, 75% of the time more than 12.4 hours was spent trying to place the pancreas. This data supports that OPOs typically start pancreas offers much more than three hours before donor surgery. The committee conjectured that allowing the OPO or Organ Center to use the facilitated allocation system at three hours before donor recovery would still give adequate time for the standard allocation system to be the primary method of organ placement.

Which populations are impacted by this Proposal?

This proposal impacts pancreas transplant candidates. As of June 30, 2015, 1,051 candidates were on the waiting list for a pancreas alone transplant in the United States. These candidates are listed at 111 different transplant programs in the United States located within 46 of the 58 donation service areas.

Pancreas transplant programs will be impacted because the qualifying criteria for the facilitative pancreas allocation list will change with this proposal. Programs that qualify for facilitated pancreas allocation may receive offers for their potential transplant recipients from OPOs as well as the Organ Center in an attempt to place the pancreas within three hours of scheduled donor recovery. Additionally, there may be some programs that previously participated in facilitated pancreas allocation that will no longer qualify under the new criteria. Restricting these offers to only programs with recent tendency to import deceased donor pancreas could increase utilization of pancreas organs. In 2014, 8,596 deceased donors had at least one organ recovered for transplant in the United States, but only 1,273 of these had their pancreas recovered for transplant (301 of them were discarded, 972 were transplanted).

Facilitated pancreas allocation currently exists only as a tool used by the Organ Center in an attempt to place pancreas organs, and results in very few transplants per year. All OPOs will be impacted by this proposal, as they will now be permitted to filter the match run using a bypass for facilitated pancreas allocation within three hours of scheduled donor organ recovery. The proposal may help OPOs place more pancreas organs for transplant by having an expedited placement to programs with a record of importing pancreas organs.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* Facilitated pancreas allocation enhances the efficiency of organ offers and acceptances by prioritizing programs that, based on past behavior, are more likely to accept and transplant an imported pancreas. This allocation sequence could possibly minimize organ discard rates and failed offers, leading to an increase in the total number of successful pancreas transplants.

2. *Improve equity in access to transplants:* There is no impact to this goal.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.

4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.

5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

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

The Pancreas Transplantation Committee will monitor this proposal by studying annual transplant volumes that are placed with facilitated pancreas allocation, as well as the proportion of transplants performed with facilitated allocation with respect to overall pancreas transplants. The Committee will also evaluate whether or not five import transplants per year is an acceptable threshold for qualification. Trends in overall pancreas transplant volumes and deceased donor utilization will be taken into account when assessing the appropriateness of the threshold for qualification. The number of programs that qualify for facilitated pancreas allocation will also be monitored. The Committee will also monitor whether or not programs that qualify are accepting offers that they receive from facilitated pancreas allocation. Since the ability for OPOs to use facilitated pancreas allocation will be new from this proposal, the committee will also monitor the frequency that each OPO uses this allocation system.

How will the OPTN implement this proposal?

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in December 2015. If passed, the proposal will go into effect after implementing IT programming. This proposal will require programming in UNet^{SM}. UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). The IT estimate for this proposal is small.

The OPTN will implement this proposal by making subtle adjustments to the current facilitated pancreas allocation scheme. The entities most impacted by these changes include:

The Organ Center – will retain the ability to make organ offers through the facilitated list. However, it will no longer do so exclusively. OPOs will now share the responsibility of being able to make these same offers.

UNOS Research – will reevaluate all pancreas programs every calendar year. Upon doing so, it will provide to UNOS IT the most up to date list of qualified programs.

UNOS IT – will receive updated eligibility statuses from UNOS Research every calendar year whereupon it will modify the facilitated pancreas allocation list in UNet℠. IT will make the facilitated pancreas allocation "button" in DonorNet that is currently accessible only to the Organ Center accessible to OPOs.

UNOS Instructional Innovations – will follow established protocols to inform members of the policy changes through Policy Notices (and System Notices). This proposal will also be monitored for potential instructional opportunities, in order to give members, professionals and the transplant community an avenue to gain information, ask questions, and modify process, if necessary. This proposal will continue to be monitored for instructional resources needs.

How will members implement this proposal?

The following explains the implementation steps to be taken by each member group:

OPOs – will need to be aware of their authority to make facilitated pancreas offers in order of the match run. Additionally, staff making these offers will need to keep in mind a timeframe change within which offers can be issued. This change allows for offers to be made within three hours of a scheduled organ donor recovery.

Pancreas Transplant Programs – will be required to collect, maintain, and submit to the OPTN all records of imported pancreas transplants on an annual basis, as they normally do. These data will be used to determine program eligibility for inclusion in the facilitated pancreas allocation list for the next calendar year. A transplant program qualifies to receive facilitated pancreas offers if in at least one of the two previous years it has transplanted a minimum of five pancreata recovered from deceased donors outside the transplant program's DSA.

Labs – will not be required to make any notable changes.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine site surveys of OPTN members. Any data entered in UNet℠ may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Language

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

11.7 ~~Administrative Rules~~ Facilitated Pancreas Allocation

11.7.A ~~Facilitated Pancreas Allocation~~ Transplant Program Qualifications

~~The~~ A transplant ~~hospital~~ program ~~must have a written agreement to participate in Facilitated Pancreas Allocation.~~ qualifies to receive facilitated pancreas offers if in at least one of the two previous years it has transplanted a minimum of five pancreas recovered from deceased donors outside its DSA. This includes pancreas transplanted as part of a multi-organ transplant.

~~The OPO can use Facilitated Pancreas Allocation to allocate a pancreas if either occurs:~~

- ~~No candidate accepts a pancreas offer from the Organ Center within five hours of the first offer~~
- ~~The Organ Center is notified that procurement of the pancreas will occur within one hour~~

~~The Organ Center must then offer the pancreas to pancreas candidates in the order of the match run who meet the following criteria:~~

~~1. Have not previously received an offer for that pancreas.~~
~~2. Are registered at a transplant hospital that previously agreed to accept any pancreas offered using the Facilitated Pancreas Allocation and that may have been procured outside of the transplant hospital's DSA.~~

Transplant programs that qualify for facilitated pancreas allocation must notify the OPTN Contractor in writing if they do not wish to participate.

11.7.B Facilitated Pancreas Offers

OPOs and the Organ Center are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or Organ Center must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run.

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