# Briefing to the OPTN Board of Directors on Distribution of Kidneys and Pancreata from Alaska

**OPTN Kidney Transplantation and Pancreas Transplantation Committees** 

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# Distribution of Kidneys and Pancreata from Alaska

Affected Policies:

Sponsoring Committee: Public Comment Period: Board of Directors Date: Policy 8.7.C: Location of Donor Hospitals Policy 11.8.A: Location of Donor Hospitals Kidney Transplantation and Pancreas Transplantation January 22, 2020 – March 24, 2020 June 8, 2020

### **Executive Summary**

In December 2019, the OPTN Board of Directors approved policy changes to remove donor service area (DSA) and region from kidney and pancreas allocation. These changes are projected to be implemented in December 2020. Under current policy, donor organs from Alaska are allocated in the DSA that includes Alaska. The first unit of allocation is changing from DSA (which, for Alaska, includes most of Washington, parts of Idaho, and all of Montana) to a 250 nautical mile (NM) circle with the donor hospital at its center. Alaska has several donor hospitals; however, it does not currently have any transplant programs. Therefore, in the absence of any transplant programs within a 250NM radius, all kidney and pancreas offers from Alaska would be offered nationally.

If allocation is not modified to reflect priority for candidates of closer proximity to Alaska, utilization could be impacted negatively. These organs already accrue significant ischemic time because the total straight flight distance from Anchorage to Seattle is 1,250 nautical miles. Therefore, the OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committees (the Committees) propose modifying the Board-approved policy to administratively allocate kidneys and pancreata from Alaska as though they were recovered from Seattle-Tacoma Airport (SeaTac), where most kidneys and pancreata are flown currently. Therefore, SeaTac would serve as the donor hospital at the center of a 250NM circle for the purposes of allocation of donor organs recovered from Alaska.

This proposed policy is a step to maximize the utilization of deceased donor organs procured in the state of Alaska and avoid unnecessary delays in placement that contributes to organ wastage in accordance with the OPTN Final Rule.

## Background

The Kidney-Pancreas Workgroup (KP Workgroup) was created in July 2018 to address the removal of DSA and region from kidney and pancreas policy.<sup>1</sup> The Workgroup also identified addressing Alaska donors in new allocation policies at the outset of deliberations about removing DSA and Region from allocation policy as a KP Workgroup member expressed concern that Alaska would no longer provide local offers to Seattle and the greater Northwest under a circle-based model with a smaller allocation circle.<sup>2</sup>

During the OPTN Spring 2019 Public Comment period, three OPTN regions, including Region 6 which encompasses the Northwest, expressed the need for the Committee to further pursue an option to address donor organs in Alaska.<sup>3</sup> The Committees did not specifically address Alaskan donors in their proposal for the OPTN Fall 2019 Public Comment Period; however, feedback from the community, requesting that the Committee develop a sensible approach for allocating these organs, continued to be received. Specifically, several commenters on the OPTN Public comment website expressed concern that these donors were not explicitly addressed in the proposal.<sup>4</sup> Region 6 noted the absence of an approach as well, suggesting that the Sea-Tac airport be used as the center of any allocation circle developed by the Committee.<sup>5</sup> Additionally, the OPTN Minority Affairs Committee stated concerns that Alaska donors would go straight to national allocation, and that this could potentially be an inefficient allocation method that could contribute to ischemic time.<sup>6</sup>

The Committees considered the negative effects of longer cold ischemic times on transplant outcomes and offer acceptance during the development of the "Eliminate the Use of DSA and Region from Kidney/Pancreas Allocation Policy" projects.<sup>7,8</sup> The same considerations still apply in the case of organs procured in Alaska; however, the risks are magnified because these organs have no opportunity to be initially allocated within a 250 NM circle before traveling 1,250 NM to the contiguous United States.

In 2018 there were 30 kidney deceased donors from Alaska. There were 31 such donors in 2017, 22 in 2016 and 20 in 2015.<sup>9</sup> The Kidney Committee deliberated the option of using Sea-Tac airport as the center of the allocation circle for these donors as well as whether proximity points should be utilized for this type of allocation. The Kidney Committee agreed that, given the long travel time these kidneys may have already accrued, it would be prudent to include proximity points in order to mitigate any further cold ischemic time, thereby increasing the likelihood that the organs would be transplanted, and

<sup>&</sup>lt;sup>1</sup> August 7, 2018, KP Workgroup Meeting Summary. Available at https://optn.transplant.hrsa.gov/ (accessed December 19, 2019).

<sup>&</sup>lt;sup>2</sup> August 28, 2018, OPTN Ad Hoc Geography Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed November 14, 2019).

<sup>&</sup>lt;sup>3</sup> OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

<sup>&</sup>lt;sup>4</sup> OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

⁵ Ibid.

<sup>&</sup>lt;sup>6</sup> Ibid.

<sup>&</sup>lt;sup>7</sup> Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee, November 2019, https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/ (accessed April

<sup>28, 2020)</sup> 

<sup>&</sup>lt;sup>8</sup> Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee, November 2019,

https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-pancreas-allocation-policy/ (accessed April 28, 2020)

<sup>&</sup>lt;sup>9</sup> Wilk, Amber. UNOS Research, 2019 OPTN data.

decreasing the likelihood that they would be discarded due to too much cold ischemic time.<sup>10,11</sup> This is in accordance with the use of proximity points in the Board-approved policies removing DSA and region.<sup>12,13</sup> Based on the Committee's discussion, language was included adding an administrative rule to the policy proposal treating Alaska donors as from Sea-Tac. The Kidney Committee approved the proposed changes removing DSA and region from policy and including the administrative rule for Alaska donors.<sup>14</sup>

The Pancreas Committee also elected to include in their proposal a new administrative rule, similar to Board-approved liver policy, which would allow organs recovered in Alaska to be allocated as if they were located at Sea-Tac Airport in Seattle, Washington, with the circle (which has a radius of 250 NM) surrounding that location. <sup>15,16</sup> There were 2 pancreas deceased donors in 2018, 3 in 2017, 6 in 2016 and 5 in 2015.<sup>17</sup> Region 6 members expressed, based on their clinical and operational experience, that this practice should be adopted in order to maintain utilization of these pancreata in an allocation system without DSA and region.<sup>18</sup> This clinical judgment is consistent with the Committees assessment during previous policy development of the new allocation policies that pancreas tolerance is lower for ischemic time and a limiting factor for travel distance.<sup>19</sup> This change will maintain consistency for distribution of abdominal organs recovered from Alaska.

Subsequent to their October meetings, the Committees received and considered feedback suggesting public consideration and comment would be prudent for the Sea-Tac change. The Committees agreed that the change to how Alaska donors are allocated should be put forward for public comment, rather than included in the removal of DSA allocation proposal that went to the Board in December of 2019. Both Committees voted on amended language that omitted the Alaska change at November 18 and 20 teleconferences (for kidney and pancreas, respectively). The approach was released as a standalone public comment policy proposal in January, 2020.

### Purpose

The committees are seeking to maximize utilization of organs procured in Alaska and increase the efficient placement of organs. In their judgement the best way to achieve that goal is by administratively

<sup>&</sup>lt;sup>10</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020).

<sup>&</sup>lt;sup>11</sup> Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution, OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney\_pancreas\_publiccomment\_20190122.pdf (accessed April 28, 2019).

<sup>&</sup>lt;sup>12</sup> Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee, November 2019,

https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/ (accessed April 28, 2020)

<sup>&</sup>lt;sup>13</sup> Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee, November 2019,

https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-pancreas-allocation-policy/ (accessed April 28, 2020)

<sup>&</sup>lt;sup>14</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020).

<sup>&</sup>lt;sup>15</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020).

<sup>&</sup>lt;sup>16</sup> December 3-4, 2018, OPTN Board of Directors Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020). <sup>17</sup> Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>&</sup>lt;sup>18</sup> OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed April 28, 2020).

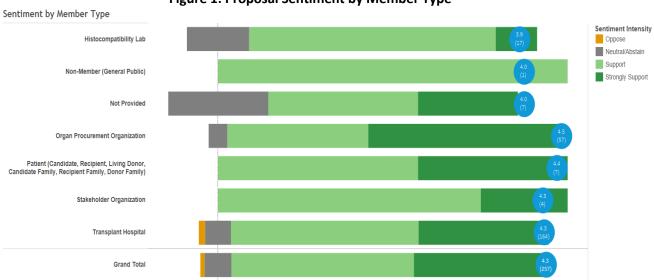
<sup>&</sup>lt;sup>19</sup> Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution, OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney\_pancreas\_publiccomment\_20190122.pdf (accessed April 28, 2019).

allocating kidney and pancreata from Alaska as though they were recovered in Seattle, which is where most of the Alaska organs are flown now.

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The Board of Directors shall be responsible for developing...[p]olicies for the equitable allocation of cadaveric organs..."<sup>20</sup>

## **Public Comment Sentiment**

Overall, the proposal was broadly supported by the community with all eleven OPTN regions voting in support. Due to the pandemic, regions 9, 10, and 11 were held as virtual meetings. The Minority Affairs, Organ Procurement Organization, and Operations and Safety Committees all reviewed and supported the proposal. Several societies commented in support as well, including NATCO, American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), and American Nephrology Nurses Association (ANNA). Multiple comments indicated how this policy would allow kidneys and pancreata to be allocated from Alaska consistently with current liver policy. There were no modifications or changes considered for the proposal post-public comment.

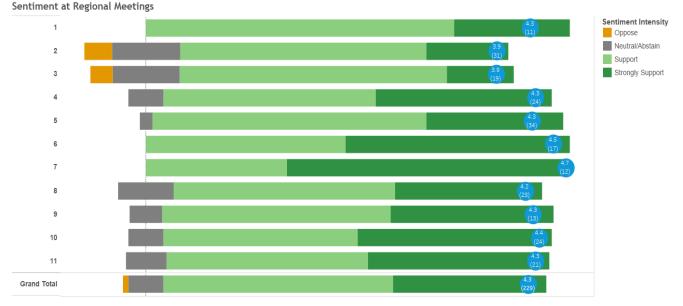


#### Figure 1: Proposal Sentiment by Member Type<sup>21</sup>

<sup>20 42</sup> C.F.R. §121.4(a)(1)

<sup>&</sup>lt;sup>21</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Sentiment at Committee Meetings



#### Figure 2: Proposal Sentiment at Regional Meetings<sup>22</sup>



 
 OPO
 45 (9)
 Settiment Intensity IntertalAbstain Support

 Ops and Safety
 47 (13)
 Settiment Intensity IntertalAbstain Support

 Grand Total
 45 (22)

### **Proposal for Board Consideration**

The Committees propose a policy specifying that organs recovered in Alaska be allocated as if they were procured at Sea-Tac Airport in Seattle, Washington.

The policy proposal is consistent with the new policies to remove DSA and region from kidney and pancreas allocation policy and for kidneys and pancreata recovered from Alaska, Sea-Tac will serve as center of the 250 NM circle. Proximity points will decrease linearly based on proximity of the candidate's hospital to that location. This approach for Alaska donors aligns with the Board-approved allocation

<sup>&</sup>lt;sup>22</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

<sup>&</sup>lt;sup>23</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for committees only includes attendees at that committee meeting. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

policies.<sup>24,25</sup> Public comment was universally supportive of the proposal and the committee did not consider nor make any changes post public comment.

### **OPTN Final Rule Analysis**

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- Is based on sound medical judgment<sup>26</sup> because organs that have initially accrued significant ischemic time are more likely to be utilized if organ offers are prioritized to programs with minimal travel distance. Increased cold ischemic time is associated with poor post-transplant outcomes, graft failure and organ discards.<sup>27</sup> As cold ischemic time is related to travel distance, in order to maximize utilization for organs that have already traveled 1,250 NM it is necessary to minimize any further cold ischemic time and travel distance. This conclusion is based in data and informed by the committee members' own clinical experience and acceptance practices.<sup>28</sup>
- Seeks to achieve the best use of donated organs<sup>29</sup> by ensuring that recovered organs are transplanted into the most prioritized candidates that are most likely to accept the organs based on the amount of cold ischemic time that will have already accrued by the time the organs arrive at Sea-Tac. Previous analysis by the Committees only demonstrated that waitlist mortality rates remained relatively unchanged as travel distance increased up to 500 NM and did not analyze up to 1,250 NM or the travel distance between Anchorage and SeaTac. However as organ utilization is negatively impacted by cold ischemic time and travel distance, minimizing the effects of these factors is a critical component to waitlist mortality rates.<sup>30</sup>

<sup>&</sup>lt;sup>24</sup> Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee, November 2019,

https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/ (accessed April 28, 2020)

<sup>&</sup>lt;sup>25</sup> Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee, November 2019, https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-pancreas-allocation-policy/ (accessed April 28, 2020)

<sup>26</sup> CFR §121.8(a)(1).

<sup>&</sup>lt;sup>27</sup> Rudolph EN, Dunn TB, Sutherland DER, Kandaswamy R, Finger EB. *Optimizing outcomes in pancreas transplantation: Impact of organ* preservation time. Clinical Transplant. 2017;31(9):10.1111/ctr.13035. doi:10.1111/ctr.13035

<sup>&</sup>lt;sup>28</sup> Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution, OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney\_pancreas\_publiccomment\_20190122.pdf (accessed April 28, 2019).

<sup>&</sup>lt;sup>29</sup>42 C.F.R. §121.8(a)(2).

<sup>&</sup>lt;sup>30</sup> Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution, OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2802/kidney\_pancreas\_publiccomment\_20190122.pdf (accessed April 28, 2019).

- Is designed to avoid wasting organs<sup>31</sup> by decreasing the number of donated organs recovered but not transplanted, thereby maximizing the utilization of organs, and minimizing the amount of discards from organs procured in Alaska. Common clinical judgment and research from 2017 indicates that long term graft survival decreases as cold ischemic time increases for simultaneous pancreas and kidney transplants as well as pancreas alone transplants. This is one factor that contributes to increased offer rejections and organ discards for organs that have accrued significant cold ischemic time.<sup>32</sup> These organs from Alaska have a long flight to the contiguous US of 1,250 NM and accrue significant ischemic time; by prioritizing organ offers to transplant programs within a 250 NM circle of the Sea-Tac, these organs are more likely to be accepted and avoid unnecessary delays caused by rejected national offers.
- Promotes the efficient management of organ placement<sup>33</sup> by taking into account the logistics of procuring and transplanting organs. For OPOs, sending out national offers without any prioritization for organs procured from Alaska is less efficient than prioritizing offers to programs near to the Sea-Tac. Transplant programs that are far away from the donor are therefore less likely to accept organs recovered in Alaska due to the amount of cold ischemic time already on them, plus the additional cold ischemic time that will accrue by the time the organ makes it from SeaTac to the final destination.
- Is designed to...promote patient access to transplantation,<sup>34</sup> and is not based on the candidate's place of residence or place of listing, except to the extent required to achieve best use of organs/avoid wasting organs/avoid futile transplants/promote candidate access to transplantation/promote efficient management of organ placement.<sup>35</sup> This proposal is in part based on a candidate's residence or place of listing to the extent that candidates that are listed within 250 NM of SeaTac are more prioritized for offers for organs from donors from Alaska. However, the best use of organs, avoiding unnecessary organ loss, promoting candidate access to transplantation and promoting the efficient management of organ placement<sup>36</sup> provide justification for constraining geographic distribution of organs due to the impact on ischemic time, travel logistics, utilization and outcomes. Specifically, organs traveling from Alaska are likely to have accrued substantial ischemic time, due to the 1,250 NM journey to the contiguous United States, which is a significant factor that warrants considering distance in allocation in order to avoid organ wastage and achieve the best use of these organs. This proposal does not promote patient access for any particular candidate group, but it weighs the balance of offering these organs from Alaska to all similarly situated candidates no matter where they are in the nation against offering to candidates as though the organ was procured in SeaTac, thus promoting access to transplant for those candidates within 250 NM of SeaTac. Within that unit of distribution, similarly situated candidates will have similar access to the organs, consistent with kidney and pancreas allocation policy.<sup>37,38</sup> The Committees believe that they have

<sup>&</sup>lt;sup>31</sup> 42 C.F.R. §121.8(a)(5).

<sup>&</sup>lt;sup>32</sup> Rudolph EN, Dunn TB, Sutherland DER, Kandaswamy R, Finger EB. *Optimizing outcomes in pancreas transplantation: Impact of organ* preservation time. Clinical Transplant. 2017;31(9):10.1111/ctr.13035. doi:10.1111/ctr.13035

<sup>&</sup>lt;sup>33</sup> 42 C.F.R. §121.8(a)(5).

<sup>&</sup>lt;sup>34</sup> Ibid.

<sup>35 42</sup> C.F.R. §121.8(a)(8).

<sup>36 42</sup> C.F.R. § 121.8(a)

<sup>&</sup>lt;sup>37</sup> Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee, November 2019, https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/ (accessed April 28, 2020)

<sup>&</sup>lt;sup>38</sup> Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee, November 2019, https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-pancreas-allocation-policy/ (accessed April 28, 2020)



appropriately considered the factors within the Final Rule and the promotion of access for candidates within this geographic unit for organs recovered from Alaska will ultimately benefit the entire system, because these organs will more likely be transplanted, and the outcomes of those transplants are more likely to be successful.<sup>39</sup>

This proposal also preserves the ability of a transplant program to decline an offer or not use the organs for a potential recipient, and it is specific to an organ type, in this case kidneys and pancreata.

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

• Designed to avoid futile transplants<sup>40</sup>

The Committees considered "whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies."<sup>41</sup> The Committees established that no specific candidate population would be less favorably impacted upon implementation of this policy, due in part to the fact that kidneys and pancreata are currently allocated in a similar geographical area based in Washington under the DSA based allocation system and the effects of this policy will not disadvantage any one candidate subgroup. Thus, the Committee determined that a transition procedure is not appropriate.<sup>42,43</sup>

### Alignment with OPTN Strategic Plan<sup>44</sup>

1. Promote the efficient management of the OPTN

This policy seeks to promote the efficient management of the OPTN by prioritizing organ allocation to a 250 NM circle centered on the Sea-Tac airport in order to minimize the amount of total ischemic time for organs that would otherwise be offered nationally. The flight from Anchorage to Seattle is 1,250 NM which indicates increased ischemic time for these organs procured in Alaska. Therefore, it is more efficient for these organs to be allocated near their arrival point in the contiguous United States before being offered nationally.

<sup>&</sup>lt;sup>39</sup> May 29, 2019, OPTN Kidney-Pancreas Workgroup Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020). <sup>40</sup> 42 C.F.R §121.8(a)(5).

<sup>&</sup>lt;sup>41</sup> 42 C.F.R. §121.8(d)

<sup>&</sup>lt;sup>42</sup> April 22, 2019 OPTN Kidney Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020).

<sup>&</sup>lt;sup>43</sup> April 16, 2019 OPTN Pancreas Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov/</u> (accessed April 28, 2020).

<sup>&</sup>lt;sup>44</sup>For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

### **Implementation Considerations**

#### Member and OPTN Operations

#### **Operations affecting Organ Procurement Organizations**

OPO staff may require training and communication about the new policies. Most of the impact will be on OPOs within 250 NM of the initial distribution unit of Sea-Tac, specifically LifeCenter Northwest which as the OPO encompassing Sea-Tac will be the primary allocator of these organs.

#### **Operations affecting Transplant Hospitals**

Transplant programs within 250 NM of the Sea-Tac may be impacted with organ offers that originated in Alaska. However, all programs should be aware and informed that the distance between the program and the organs recovered from Alaska is determined based on the location of the Sea-Tac airport, and the effect that could have on ischemic time.

#### Operations affecting the OPTN

Programming changes will be required for this proposal. This would be a "small" size effort in terms of IT implementation. UNOS will follow established protocols to inform members of any policy changes through Policy Notices.

#### **Operations affecting Histocompatibility Laboratories**

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

#### **Projected Fiscal Impact**

#### Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on organ procurement organizations.

#### Projected Impact on Transplant Hospitals

This proposal is not anticipated to have any fiscal impact on transplant hospitals.

#### Projected Impact on the OPTN

Policy and Community Relations prepared and executed internal team and Committee meetings and produced policy associated documents for the proposal that will establish a base location for allocating kidneys and pancreata from Alaska.

A Very Small IT implementation effort includes resources for one programmer and one tester. Communications anticipates a small effort involving a system notice and an email.

There is minimal ongoing effort expected from Research and IT, with Research estimating 30 hours to annually monitor as part of the overall Kidney and Pancreas DSA proposals currently going to the Board of Directors.

#### Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

## **Post-implementation Monitoring**

#### **Member Compliance**

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."<sup>45</sup>

This proposal will not change the current routine monitoring of members. All policy requirements, as well as any data entered in UNet<sup>™</sup>, may be subject to OPTN review, and members are required to provide documentation as requested. OPTN contractor staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and staff will continue to investigate potential policy violations.

#### **Policy Evaluation**

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."<sup>46</sup> This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post implementation. The following metrics, and any subsequently requested by the Committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet (e.g., TIEDI forms may take 60+ days to be submitted)) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy:

- # and % of kidney and pancreas donors recovered in Alaska
- # and % of kidneys and pancreata recovered in Alaska
- # and % of kidney and pancreas transplants performed from donors recovered in Alaska
- # and % of kidneys and pancreata transplanted inside/outside fixed circle of Sea-Tac.
- Distribution of kidney and pancreas travel distance (NM) for transplants performed from donors recovered in Alaska

### Conclusion

Kidneys and pancreata recovered from Alaska accrue significant ischemic time due to the distance from Alaska to the contiguous U.S. There are no transplant programs in Alaska. To promote efficient placement of organs and avoid unnecessary organ loss, the Committees propose administratively allocating kidneys and pancreata recovered from Alaskan donors from the Sea-Tac airport in Seattle, Washington. This policy promotes the efficient placement, and avoids the wastage, of organs in accordance with the Final Rule by prioritizing offers to transplant programs within 250 NM of the point of arrival in the contiguous US for kidney and pancreata recovered in Alaska. By creating a system for prioritizing organ offers, this proposal will cut down on national offers that are sent to programs that

<sup>45</sup> CFR §121.8(a)(7).

<sup>46</sup> CFR §121.8(a)(6).



would likely not accept the organs due to the significant ischemic time and distance, further improving OPTN efficiency by avoiding the delays associated with multiple organ offer rejections.

# **Policy Language**

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (<del>example</del>). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 8.7 Administrative Rules

2	8.7.C Location of Donor Hospitals
3	For the purpose of determining the location of the donor hospital, kidneys procured in Alaska
4	will be considered procured from the Sea-Tac Airport, Seattle, Washington.
5	
6	11.8 Administrative Rules
7	11.8.A Location of Donor Hospitals
8	For the purpose of determining the location of the donor hospital for allocation of pancreas,
9	kidney-pancreas, or islets, kidneys and pancreata procured in Alaska will be considered procurec
10	from the Sea-Tac Airport, Seattle, Washington.
11	
12	#
13	