

Title: Distribution of Kidneys and Pancreata from Alaska

**Sponsoring Committees:** Kidney Transplantation and Pancreas Transplantation

## What is current policy and why change it?

Deceased donor kidneys and pancreata from donors in Alaska are first offered to candidates in a designated Donation Service Area (DSA), which helps prevent the organ traveling further to go to a patient in similar need. A new policy will replace DSA with a 250 nautical mile circle around the donor hospital. When this changes, because there are no transplant hospitals in Alaska, there will not be any transplant hospitals located within 250 nautical miles of donor hospitals in Alaska. Without a policy change, all organs procured in Alaska would be offered nationally, which could create inefficiencies in organ placement. This means that these organs could be offered to a patient in Florida before a very similar patient in California if not addressed by a modification of policy.

## What's the proposal?

• The **Seattle-Tacoma International Airport (Sea-Tac)** would be a substitute for the donor hospitals in Alaska as the center of the 250 nautical mile circle

## What's the anticipated impact of this change?

- What it's expected to do
  - o Promote the efficient placement of kidneys and pancreata from donors in Alaska
- What it won't do
  - o Affect the placement of organs donated anywhere other than Alaska

## Themes to consider

How this would impact efficient placement of organs

## Terms you need to know

- <u>Donation Service Area</u>: The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals
- <u>Donor hospital</u>: The hospital where the deceased or living donor is admitted
- Nautical mile: Equal to 1.15 miles and is directly related to latitude and longitude; used in aviation

• Click here to search the OPTN glossary



## **Public Comment Proposal**

# 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: Policy 8.7.C: Location of Donor Hospitals

Policy 11.8.A: Location of Donor Hospitals

Sponsoring Committee: Kidney Transplantation and Pancreas Transplantation

Public Comment Period: January 22, 2020 – March 24, 2020

## **Executive Summary**

In December 2019, the OPTN Board of Directors approved policy changes to removes DSA and region from kidney and pancreas allocation. Currently, donors from Alaska are allocated in a DSA that includes areas of the Pacific Northwest. The local unit is changing from DSA (which currently includes most of Washington, parts of Idaho, and all of Montana) to a 250 nautical mile (NM) circle. Alaska does not have any transplant programs. Therefore, in the absence of any transplant programs within a 250NM radius, all kidney and pancreas offers from Alaska will be first offered nationally if this change isn't made.

If allocation is not modified to reflect priority for candidates of closer proximity to Alaska, utilization could be impacted. The 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 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.

This proposed solution promotes efficient placement of organs and avoiding unnecessary organ loss, in accordance with the OPTN Final Rule.

## **Purpose of the Proposal**

DSA and region are being removed from kidney and pancreas allocation policy, and Alaska donors will no longer be allocated in a DSA or region closer to Alaska than other parts of the continental U.S. Without modification to policy, kidneys and pancreata from Alaska donors could accrue additional ischemic time because here are no transplant programs in Alaska and organs could be shipped a significantly further distance to candidates with similar medical priority. Specifically, Alaska organs could be allocated at a national scale before offers go to candidates closer to the geographically-isolated region.

The proposed solution seeks to avoid a negative impact on utilization and efficient placement of organs recovered in Alaska by administratively allocating kidney and pancreata from Alaska as though they were recovered in Seattle, which is where most of the Alaska organs are flown now.

## **Background**

The Kidney-Pancreas Workgroup (KP Workgroup) identified addressing Alaska donors in new allocation policies at the outset of deliberations about removing DSA and Region from allocation policy. A KP Workgroup members expressed concern that Alaska would no longer provide local offers to Seattle under a concentric circle model with a small local circle. At the time, the Ad Hoc Geography was considering options to address geographically isolated hospitals uniformly across all organ types, and the KP Workgroup elected to wait for a recommendation from that committee. <sup>2</sup>

During the OPTN Spring 2019 Public Comment period, three OPTN regions, including Region 6, expressed the need for the Committee to further pursue an option to address donors 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 solution for 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 a solution 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.<sup>6</sup>

The Committees considered this feedback at their in-person meetings in October 2019.<sup>7,8</sup> Kidney Committee members from Region 6 expressed the necessity of addressing this problem in order to

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

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

<sup>&</sup>lt;sup>3</sup> OPTN Public Comment, Available at <a href="https://optn.transplant.hrsa.gov/">https://optn.transplant.hrsa.gov/</a> (accessed November 14, 2019).

<sup>&</sup>lt;sup>4</sup> OPTN Public Comment, Available at https://optn.transplant.hrsa.gov/ (accessed November 14, 2019).

<sup>&</sup>lt;sup>5</sup> Ibid.

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

<sup>&</sup>lt;sup>7</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <a href="https://optn.transplant.hrsa.gov/">https://optn.transplant.hrsa.gov/</a>. (Accessed December 19, 2019).

<sup>&</sup>lt;sup>8</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <a href="https://optn.transplant.hrsa.gov/">https://optn.transplant.hrsa.gov/</a> (Accessed December 19, 2019).

maximize the utilization of kidneys from Alaska. In 2018 there were 30 kidney deceased donors from Alaska. There were 31 such donors in 2017, 22 in 2016 and 20 in 2015. 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. This is in accordance with the use of proximity points in the Board-approved policy removing DSA and region. Based on the Committee's discussion, language was included adding an administrative rule to the 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 with 13 votes in support and 4 votes in dissent.

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>12,13</sup> There were 2 pancreas deceased donors in 2018, 3 in 2017, 6 in 2016 and 5 in 2015. <sup>14</sup> Region 6 expressed that this practice should be adopted in order to maintain utilization of these pancreata in an allocation system without DSA and region. This change will bring consistency to 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. Both Committees voted on amended language that omitted the Alaska change at November 18 and 20 teleconferences (for kidney and pancreas, respectively).

## **Proposal**

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

The proposed solution is consistent with the solution to remove DSA and region from policy and allocate instead using a 250 NM circle with up to two points inside the circle and up to four points outside the circle. For purposes of 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 policy.

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

<sup>&</sup>lt;sup>10</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <a href="https://optn.transplant.hrsa.gov/">https://optn.transplant.hrsa.gov/</a> (accessed December 20, 2019).

<sup>11</sup> Ibid.

<sup>&</sup>lt;sup>12</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <a href="https://optn.transplant.hrsa.gov/">https://optn.transplant.hrsa.gov/</a> (accessed December 20, 2019).

<sup>&</sup>lt;sup>13</sup> December 3-4, 2018, OPTN Board of Directors Meeting Summary. Available at <a href="https://optn.transplant.hrsa.gov/">https://optn.transplant.hrsa.gov/</a> (accessed October 31, 2019).

<sup>&</sup>lt;sup>14</sup> Wilk, Amber. UNOS Research, 2019 OPTN data.

#### Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed "in accordance with §121.4", which in turn incorporates the requirements in §121.8 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 addresses the requirements of the Final Rule by promoting the efficient management and avoiding unnecessary organ loss. By allocating organs as if they were procured from Sea-Tac airport instead of a transplant hospital in Alaska, these kidney and pancreata could be allocated to local candidates in closer proximity to the place of procurement before being offered nationally. Recognizing that there is currently no transplant programs in Alaska such organs will have several hours of cold ischemic time by the time they reach Sea-Tac airport and be allocated, it promotes more efficient management to propose policy that would prevent adding further ischemic time to promote the utilization of these organs.

#### **Potential Impact on Select Patient Populations**

This proposal impacts all kidney and pancreas candidates who could have received an offer from an organ recovered in Alaska. However, the Committees agrees that considerations of ischemic time could prevent utilization of Alaska-recovered organs for candidates in, for example, Florida, because of cold ischemic time and concerns about organ loss. Candidates in the Pacific Northwest would continue to have additional access to organs recovered in Alaska, which would be modified so candidates closer to Sea-Tac would receive additional priority. The Committees consider that this proposal will lead to fewer non-utilized kidneys and pancreata that are donated in Alaska.

## **Implementation and Operational Considerations**

#### **OPTN Actions**

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 and educate them on any policy changes through Policy Notices. UNOS Professional Education will monitor for additional educational needs throughout the development of this proposal.

#### **Member Actions**

Transplant programs and OPO staff may require training and communication about the new policies, with most of the impact being on OPOs and transplant programs within 250 NM or the initial distribution unit of Sea-Tac. However, all programs and OPOs should be aware and informed that the distance between the program or OPO and the organs recovered from Alaska is determined based on the location of the Sea-Tac airport, and the affect that could have on ischemic time.

## **Post-implementation Monitoring**

#### **Member Compliance**

No new policy compliance requirements will arise as a result of this policy change.

#### **Policy Evaluation**

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 continental U.S. There are no transplant programs in Alaska. To avoid these organs accruing ischemic time that leads to unnecessary organ loss, the Committees propose administratively allocating kidneys and pancreata recovered from Alaskan donors as from the Sea-Tac airport in Seattle, Washington. This solution prevents organs being transported a significant distance to a candidate with a similar waiting time, promoting efficiency of organ placement in accordance with the Final Rule.



## **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.

#### 8.7 Administrative Rules

-	<u></u>
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 procured
10	from the Sea-Tac Airport, Seattle, Washington.
11	
12	#