

**Title:** Modifications to Released Kidney and Pancreas Allocation **Sponsoring Committee:** Organ Procurement Organization

## What is current policy and why change it?

If a transplant hospital is unable to transplant a kidney or pancreas into the patient they accepted the organ for, they must contact the Organ Procurement Organization (OPO) that offered them the organ so that a new recipient can be found. That "host" OPO has the option to continue offering the organ or they can delegate that responsibility to the "importing" OPO that serves the transplant center that declined the organ. The importing OPO then runs a list of eligible candidates within their Donation Service Area (DSA) to hopefully find another recipient that is close-by.

The OPTN Board of Directors approved policy in December 2019 that removes DSA and region from OPTN kidney and pancreas allocation policy and instead uses a 250 nautical mile (NM) circle with the donor hospital at the center. Having policies for **reallocation** of a kidney or pancreas that are consistent with the Board-approved changes promotes efficiency and organ utilization.

## What's the proposal?

- Host OPO would have 2 options when an original recipient can't receive intended kidney or pancreas:
  - o **Continue** to find a new recipient
  - Delegate responsibility to the UNOS Organ Center
- If host OPO decides to continue to find new recipient, they can:
  - Use the **original match run**; or
  - Create a **new match run** based on the transplant hospital that originally accepted the organ
    - Offers organ to patients within a 250NM circle of the donor hospital first
    - Candidates inside the circle receive up to 2 proximity points based on how close their transplant hospital is to the center of the circle
    - If no candidate within the circle accepts the organ it would then be offered to patients outside of the circle
    - These candidates could receive up to 4 proximity points

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

- <u>What it's expected to do</u>
  - Create a process for reallocation of organs from candidates who cannot be transplanted that aligns with the new kidney and pancreas allocation policies

## Themes to consider

- The circle size for reallocation
- Should the process be the same for kidney and pancreas
- Who should be responsible for reallocating the organ(s)

## Terms you need to know

- <u>Match run:</u> A computerized ranking of transplant candidates for an organ being offered based upon donor and candidate medical compatibility and criteria defined in OPTN policies.
- **Nautical Mile:** Equal to 1.15 miles and is directly related to latitude and longitude; used in aviation.
- **<u>Proximity Points</u>**: additional points given to transplant candidates on a match run based off of the location of their transplant hospital in relation to the center of the allocation circle. The closer to the center of the circle, the more points a candidate receives.
- **<u>Reallocation</u>**: The process of finding the next suitable transplant candidate for an organ after it has been accepted and then declined for the original intended recipient.
- <u>Click here to search the OPTN glossary</u>

## Public Comment Proposal

## Modifications to Released Kidney and Pancreas Allocation

**OPTN Organ Procurement Organization Committee** 

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# OPTN

## Modifications to Released Kidney and Pancreas Allocation

Affected Policies:	<ul> <li>5.9: Released Organs</li> <li>8.3: Kidney Allocation Score</li> <li>8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%</li> <li>8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores</li> <li>Greater Than 20% But Less Than 35%</li> <li>8.5.J: Allocation of Kidneys from Deceased Donors with KDPI Scores</li> <li>Greater than or Equal to 35% but Less than or Equal to 85%</li> <li>8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores</li> <li>Greater than 85%</li> <li>11.2: Pancreas Allocation Score</li> <li>11.4.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or</li> </ul>
Sponsoring Committee: Public Comment Period:	Equal To 30 kg/m <sup>2</sup> 11.4.G: Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m <sup>2</sup> Organ Procurement Organization January 22, 2020 – March 24, 2020

### **Executive Summary**

Reallocation refers to situations in which an organ allocated to an original intended recipient is unable to be transplanted in that recipient. In current policy, the host OPO that allocated the organ to the intended recipient's transplant hospital may continue allocating according to the original match run, or allow the organ to be allocated by the OPO in the DSA of the transplant program that originally accepted and then released the organ. Because DSA is being removed from both kidney and pancreas policy, policy needs to be updated to reflect a circle-based approach to reallocate organs not transplanted in their intended recipients. This is particularly a problem in kidney allocation because of the volume of reallocated kidneys compared to other organs.<sup>1</sup> Utilization is a concern in the pancreas community. While pancreata are less likely to be reallocated because of ischemic time, utilization concerns imply that even a small decrease in utilization would be unacceptable to the community.<sup>2</sup> Furthermore, kidney and pancreas allocation are intertwined, in that a majority of pancreas transplants are performed as simultaneous pancreas-kidneys (SPKs). Therefore, both kidney and pancreas would benefit from a solution that improves efficiency and avoids unnecessary organ loss by addressing situations of reallocation.

The proposed solution retains the responsibility to reallocate a previously accepted organ with the host OPO that originally allocated the organ to the intended recipient's transplant hospital. The Committee considers that the host OPO retaining responsibility for reallocation avoids inefficiencies and added

<sup>&</sup>lt;sup>1</sup>2018 OPTN data

<sup>&</sup>lt;sup>2</sup> Stratta, Robert J., Jonathan A. Fridell, Angelika C. Gruessner, Jon S. Odorico, and Rainer W.g. Gruessner. Pancreas transplantation: A Decade of Decline. *Current Opinion in Organ Transplantation* 21, no. 4 (August 2016): 386-92. doi:10.1097/mot.00000000000319.

complexity. The host OPO may continue allocation using the original match run, use a match run based around the transplant program that released the organ, or delegate to the OPTN (the UNOS Organ Center). The new released organ match run would utilize a straight line distance of 250 nautical mile (NM) around the transplant program, with up to two proximity points inside the 250 NM circle and up to four points outside the circle, depending on the proximity of the candidate's hospital to the transplant program.

The OPO Committee appreciates all feedback related to this proposal, but in particular asks for feedback on the following:

- Do you agree with the host OPO retaining responsibility for reallocation instead of delegating to the OPO in the DSA of the transplant program that originally accepted the organ? If not, please state why.
- Do you agree with a reallocation circle of 250 NM around the transplant program with proximity points inside and outside the circle? If not please state your alternative.
- What operational challenges would the new system incur for you? Specifically, what are the operational challenges related to having new "backup" match runs generated that include offers already screened off?
- In addition to the host OPO being able to continue down the original match run or run a new match run around the transplant program that released the organ, does a third option need to be identified in policy for situations in which it would be appropriate to allow center backup? For example, a high kidney donor profile index (KDPI) kidney placed beyond 250 NM.
- Do you have concerns about cross matching under the proposed solution, or anticipate more use of virtual cross matching?
- Do you agree it is appropriate having the same solution for kidney and pancreas reallocation?

## **Purpose of the Proposal**

The OPTN Board of Directors approved policy in December 2019 that removes DSA and region from OPTN kidney and pancreas allocation policy. Having policies for reallocation of a kidney or pancreas that are consistent with the Board-approved changes promotes efficiency and organ utilization. Therefore, modifications to pancreas and kidney allocation policy to remove DSA and region as distribution units require the modification of policy related to the reallocation of released kidneys and pancreata, including *Policy 5.9: Released Organs*.

Released organs refer to organs released by the transplant program back to the host OPO or the OPTN (UNOS Organ Center) for reallocation. Without modification to policy on reallocation of released kidneys and pancreas, the changes to distribution in pancreas and kidney allocation imply that OPOs would have to follow the original match run to reallocate kidneys and pancreata, even when the organ(s) have accrued significant ischemic time and are far from the donor hospital around which the original match run is based. This could negatively impact patient outcomes and system efficiency with the reallocated organ traveling further and accruing more ischemic time. This could also increase the chance of organs not being used for transplantation.

### Background

#### **Kidney and Pancreas Proposals**

The Kidney and Pancreas Transplantation Committees worked together in 2018 and 2019 to identify a solution to remove DSA and region from kidney and pancreas allocation. In discussions regarding the implications of removing DSA and region, the Committees identified that reallocation policy would be impacted by replacing DSA and region with a fixed-distance circle around a donor hospital.

OPTN *Policy 5.9: Released Organs* specifies that transplant programs must let the host OPO know when an organ is not transplanted in the intended recipient. The host OPO that originally allocated the organ to the intended recipient's transplant hospital has the opportunity to continue allocating according to the original match run or delegate that responsibility to the OPO in the DSA of the transplant program that received the organ. The latter practice is known as "import backup" or "local backup" and is utilized to prevent ischemic time and inefficiencies in organ allocation by providing OPOs with options regarding what to do with organs that are not transplanted into the original, intended recipient.

To make reallocation options for kidney and pancreas consistent with the changes removing DSA and region, both the Kidney Transplantation Committee and the Pancreas Transplantation Committee included solutions in their fall 2019 public comment proposals to allow host OPOs to delegate placement of the organ to the import OPO (which is currently permissible according to *Policy 5.9: Released Organs*). The import OPO could utilize a new match run based around the transplant hospital, which would be a smaller circle than the initial distribution unit. In the fall 2019 proposals, the original allocation unit was 500 NM and the reallocation circle was 150 NM.<sup>3</sup> Both Committees agreed that with

<sup>&</sup>lt;sup>3</sup> August 2019, Proposal to Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee and Proposal to Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee. Available at <u>https://optn.transplant.hrsa.gov</u>

a 500 NM circle of distribution, the reallocation circle should be smaller to account for concerns regarding ischemic time, organ loss and efficient organ placement.

In fall 2019 public comment, feedback was mixed on the proposed solution of a 150 NM circle around the transplant program as the reallocation circle and the ability of the host OPO to delegate responsibility to the import OPO.<sup>4</sup> In particular, public comment feedback indicated some concern with the ability of the host OPO to delegate responsibility to the import OPO. The concerns related to efficiency and the fact that the import OPO would not have context related to donor characteristics and donor management that could impact efficiency and complexity of placing the organ. The Committees received mixed feedback regarding the size of the circle itself, with some support for a 150 NM circle and some concerns, particularly with pancreas, that the circle may be too big and a smaller circle (or center backup) may be more appropriate.<sup>5</sup> Center backup refers to the idea that the OPO allows the transplant program to go outside the strict sequence of the match run and use the organ in another candidate at their hospital who may be lower down the match run.

The initial kidney and pancreas public comment documents proposed replacing DSA and region with a 500 NM circle. In response to community feedback, post-public comment changes included modifying the original allocation circle from 500 NM to 250 NM with fewer proximity points inside and outside the circle (two and four, respectively). These changes reflected Final Rule considerations related to efficiency of organ placement, best use of organs, and unnecessary organ loss.

Given the Committees' post-public comment change from utilizing an initial distribution unit of 500 NM to an initial distribution unit of 250 NM, both Committees recognized that the import backup solution would need modification as well. The ischemic time accrued with a 500 NM circle differs from a 250 NM circle, which impacts how far the organ can be reallocated. Thus, an initial distribution unit of 250 NM changes the necessity of having a 150 NM reallocation circle, which was identified as a solution in tandem with an initial distribution unit of 500 NM. The Committees also recognized that public comment feedback was not uniform in support of the 150 NM solution, and additional conversations were needed to discuss some of the public comment received (specifically, feedback related to whether the host OPO should retain responsibility to reallocate the organ and feedback on center backup for pancreas reallocation).

#### Import Backup Workgroup

Based on these discussions, both the Kidney and Pancreas Committees agreed to remove reallocation policy language from the proposals removing DSA and region from kidney and pancreas allocation, respectively, before these proposals were presented to the OPTN Board of Directors.<sup>6</sup> A new Workgroup was formed with members from the Kidney, Pancreas, OPO, Operations and Safety, and Histocompatibility Committees to address reallocation policy for pancreas and kidney. The Workgroup members included perspectives from transplant surgeons of different organs, histocompatibility lab directors and OPOs from different regions of the country. Given their collectively varied background and experience, these stakeholders were uniquely positioned to collaborate and identify an appropriate solution to send out for public comment. Because OPOs are directly involved in the challenges and

<sup>&</sup>lt;sup>4</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov</u> <sup>5</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov</u>

<sup>&</sup>lt;sup>6</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary and October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov</u>

processes related to reallocation, the OPO Committee was identified as an appropriate sponsor for the proposed changes.

The Workgroup reviewed several options for making current reallocation policy consistent with the changes removing DSA and region from kidney and pancreas policy, as well as relevant data.

#### Supporting Data

Relevant reallocation data from 2018 included the number of kidney, kidney- pancreas, and pancreas acceptances outside the donor recovery DSA and from released organ match runs.<sup>7</sup> The number of acceptances outside a DSA give a bigger picture of the landscape of kidney and pancreas acceptance patterns:

- 6,458 (40%) kidney acceptances were from centers outside the donor recovery DSA ("non-local")
  - These acceptances encompassed 4,888 kidney matches (50%) for 3,451 kidney donors\* (41%)
- 370 (34%) KP/pancreas acceptances were from centers outside the donor recovery DSA ("non-local")
  - These acceptances encompassed 335 donors (32%)

The Workgroup also considered the specific number of acceptances that came from released organ or import match run, as these data directly relate to the impact of modifying reallocation policy:<sup>8</sup>

- 1,683 (10%) kidney acceptances came from an released organ or import (versus host) match run
  - These acceptances encompassed 1,451 kidney matches (15%) for 1,351 kidney donors (16%)
- 35 (3%) KP/pancreas acceptances came from a released organ or import (versus host) match run
  - These acceptances encompassed 35 donors (3%)

Kidney reallocation accounts for the majority of organ reallocation overall, and therefore should be modified to avoid inefficiencies in a circle-based system. Although pancreata account for much smaller proportion of reallocated organs, pancreas utilization has been a concern and a priority for the community, given the overall decline in pancreas transplantation.<sup>9</sup> Therefore, any efforts to promote efficiency and avoid organ loss are to be pursued.

#### Workgroup Discussions

The Workgroup reviewed and considered the scope of this project, which is not to address every challenge related to reallocation, but to identify a solution that brings consistency to the kidney and pancreas allocation policies that utilize fixed distance circles and not a DSA and region based system,

<sup>&</sup>lt;sup>7</sup> Urban, Read. Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>&</sup>lt;sup>8</sup> Urban, Read. Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>&</sup>lt;sup>9</sup> Stratta, Robert J., Jonathan A. Fridell, Angelika C. Gruessner, Jon S. Odorico, and Rainer W.g. Gruessner. Pancreas transplantation: A Decade of Decline. *Current Opinion in Organ Transplantation* 21, no. 4 (August 2016): 386-92. doi:10.1097/mot.00000000000319.

and to propose a reasonable solution that will avoid unnecessary organ loss.<sup>10</sup> The Workgroup also carefully considered kidney and pancreas reallocation differences. Pancreata can handle less ischemic time than kidneys, and kidneys account for a greater percent and number of reallocated organs.<sup>11</sup>

Some Workgroup members and the Pancreas Committee expressed concern that a 250 NM reallocation circle would be too large for efficient placement.<sup>12</sup> A majority of Workgroup members agreed, however, that equity concerns trumped the concerns over efficiency and utility.<sup>13</sup> The Workgroup overall agreed that community input should be solicited, especially since the proposed solution is explicit in its requirement that OPOs follow the match sequence. The proposal would only allow allocation according to the original match run or the released organ match run in cases that the organ would be reallocated. Any transplants out of sequence would be in non-compliance of policy, and potentially reviewed. However, any review of policy violations by its nature takes into account the context in which the match sequence is not followed. Since "rescue" placement during kidney allocation does happen, the Workgroup discussed whether it would be appropriate to allow a third option outside of the strict sequential order of the match run. This would allow those placements to be compliant with policy (such as allowing for center backup for high KDPI kidneys when necessary to avoid unnecessary organ loss) and agreed to ask for feedback during public comment. A question regarding a potential third option is included at the end of the Executive Summary and the Conclusion of this paper for community feedback.

Workgroup members also expressed concerns about reallocation circles overlapping with original match run circles, and including offers to candidates with refusals on the original match run.<sup>14</sup> Workgroup members indicated reviewing the same offers unnecessarily would be inefficient and could contribute to increased organ ischemic time. The challenge of implementing a system that removes refusal codes would significantly push back the proposed implementation timeline, however. The Workgroup agreed to ask the community in public comment about the impact of operational concerns related to inputting refusal codes multiple times and other operational concerns.

### **Proposal**

The proposed solution for reallocating kidneys and pancreata provides that the host OPO retain responsibility in managing reallocation of the kidney, pancreas or combined kidney-pancreas. The host OPO would retain the option to continue down the original match run, have the option to use a new released organ match run based around the transplant program that originally accepted the organ for one of their patients, or delegate to the OPTN (the UNOS Organ Center). The reallocation distribution units and proximity points would be consistent with those distribution units and proximity points used in the original match run: a straight line initial distribution unit of 250 NM with up two proximity points within 250 NM, and up to four proximity points outside 250 NM. Proximity points would decrease linearly based on the proximity of the candidate's hospital to the transplant program that originally accepted and then released the organ, and these points would only apply within allocation classifications.

<sup>&</sup>lt;sup>10</sup>November 7, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov</u> <sup>11</sup> Urban, Read. Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>&</sup>lt;sup>12</sup> November 20, 2019, OPTN Pancreas Transplantation Committee Meeting Summary and December 12, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov</u>

<sup>&</sup>lt;sup>13</sup> November 21, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <u>https://optn.transplant.hrsa.gov</u>

<sup>&</sup>lt;sup>14</sup> December 12, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at https://optn.transplant.hrsa.gov

This is the same distribution schema that will be used in kidney and pancreas allocation once DSA and region are removed from allocation policy and a circle-based system is utilized. The proposed solution serves to avoid inefficiencies and additional ischemic time that could lead to organ loss. A reallocation circle would be particularly helpful for situations in which the organ has already traveled significantly and accumulated ischemic time, and is far away from the donor hospital which is used to create the original match run. The proposed solution also avoids inefficiencies through disallowing host OPOs that originally allocated the organ to the intended recipient's transplant hospital to delegate to other OPOs that do not have context or know the history of the organ.

#### **Compliance with NOTA and the Final Rule**

The Final Rule 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."<sup>15</sup> This proposal addresses the requirements of the Final Rule.

- Shall be based on sound medical judgment: The Committee proposes this change based on the medical judgment of OPO professionals, transplant surgeons, and members of four stakeholder committees in deriving the proposed changes.
- Shall be designed to avoid wasting organs: The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to avoid organ loss by ensuring alternative allocation is available for organs that may otherwise not be utilized when ischemic time and organ quality impact availability and utilization opportunities.
- Shall be designed to...to promote the efficient management of organ placement: This proposal avoids sending organs cross-country unnecessarily by allowing the host OPO to run a match around the transplant program that accepted but can no longer use the organ.

Additionally, this proposal is consistent with other changes removing DSA and region, units of distribution that were determined to not be compliant with the Final Rule.

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

All kidney, kidney-pancreas and pancreas candidates have the potential to be impacted by this proposal in terms of offers received and how those organs are distributed. In particular, candidates within 250 NM of a transplant program that was unable to use a kidney, kidney-pancreas or pancreas may receive an offer based on their proximity to the transplant program and other donor and candidate characteristics.

<sup>15 42</sup> C.F.R. § 121.8(a)(8).

#### **Alternate Solutions Considered**

The Workgroup reviewed several alternative solutions for situations in which the kidney or pancreas is unable to be transplanted into the original intended recipient:

- 1. Host OPO continues distribution down the original match run; no reallocation alternative match run is available (make no modifications to policy)
- Host OPO may continue distribution down the original match run OR delegate to the OPO in the DSA of the transplant program that originally received the organ for one of their candidates. This other OPO runs a new match run using a distribution circle around the transplant program that originally received the organ instead of the donor hospital. The distribution circle remains the same (250 NM).
- Host OPO may continue distribution down the original match run OR runs a new match run using a distribution circle around the transplant program that originally received the organ instead of the donor hospital. The distribution circle remains the same (250 NM). In this scenario, the host OPO retains responsibility for placement of the reallocated organ instead of delegating to another OPO.

The Workgroup considered that option 1 would have negative consequences regarding efficiency of placement and potential impact on ischemic time and organ loss. This option would imply that an organ recovered in New York and sent to a candidate in California could only be reallocated according to the New York match run, with its associated proximity points around the donor hospital in New York. Thus, candidates would be receiving priority based on proximity to a donor hospital in New York, even when the organ was in California. Given the additional ischemic time that an organ may accrue during the original allocation, it seemed unacceptable to the Workgroup to disallow reallocation from a new match as an option.

The Workgroup considered option 2, but had concerns similar to those raised in public comment related to the impact of the host OPO delegating responsibility to an import OPO. Specifically, the Workgroup considered that it is important to retain responsibility with the host OPO because the host OPO is vested in the placement of that organ, having worked with the donor from the beginning, in a way that the other OPO is not. The efficiency of the reallocation may be greatly enhanced by the host OPO handling the reallocation compared to the OPO that has no background or history on the organ or the match. These concerns were raised with the public comment proposal that proposed allowing delegation of the reallocation to another OPO.

Currently, the host OPO is able to delegate to an OPO in the DSA of the transplant program that originally accepted the organ; however, the other OPO would be allocating based on its DSA, which contains programs the OPO has worked with and in a certain defined area. With a 250 NM circle, the new import match run may contain many more programs than the importing OPO's DSA. The potential for increased efficiency and the vested interest of the host OPO indicates the appropriate reallocation distribution responsibility should be kept with the host OPO.

Given the Workgroup concerns regarding delegation to the importing OPO, the Workgroup supported option 3, in which the host OPO retains responsibility and has the option of using a released organ match run based on a 250 NM circle around the transplant program that originally accepted the organ. The Workgroup agreed that 250 NM was an appropriate distance given the proximity points in place that give additional priority based on candidate proximity to the transplant program. The Workgroup

also considered it important to have the option of distribution units based around the transplant program and not around the original donor hospital because of concerns about efficiency and organ loss. Within the context of efficiency, it is also important to note that relatively few organs are expected to leave the 250 NM circle for the first allocation.<sup>16</sup>

## **Implementation and Operational Considerations**

#### **OPTN Actions**

Programming changes will be required for this proposal. This will be a "large" size effort in terms of IT implementation. Changes will be made to kidney allocation and combined kidney-pancreas & pancreas match allocation to allow host OPOs to run matches based around the transplant program that originally accepted the organ instead of around the donor hospital from which the organ was procured. 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**

Both Transplant Center and OPO staff would require training and communication about new policies.

#### **Transplant Hospitals**

Transplant programs may be impacted because of limited blood or tissue samples, which may inhibit some programs from performing testing for their potential candidates. A 250 NM circle from the transplant program could encompass a longer list of potential candidates than most DSAs, which are currently utilized for reallocation purposes. Transplant programs would be impacted if they requested blood or tissue samples but the OPO did not have enough to distribute. In practice, transplant programs may need to adjust their behavior based on limited tissue availability and the potential sensitization of their candidates, as well as the donor organ characteristics and other factors, such as where the candidates for which the testing would be performed are located on the reallocation list. Specifically, transplant programs may also increase utilization of virtual cross-matching to mitigate the effect of the policy change.

#### OPOs

OPOs will continue allocating donor organs through the match runs, and will retain responsibility to place organs even if the organ travels far from the OPO. This in practice could mean building new relationships with transplant programs outside the OPO's DSA. Additional staff or staff hours may be necessary, dependent on change in volume of reallocation under the new allocation system using a 250 NM circle around the donor hospital instead of DSA or region. In addition, OPOs placing an organ for reallocation may be challenged to distribute sufficient tissue samples for cross-matching. If tissue samples are in limited supply, the OPO would need to decide which transplant programs receive those tissue samples (programs with candidates high on the list). OPOs may need to reassess protocols regarding when to delegate to the Organ Center.

<sup>&</sup>lt;sup>16</sup> Scientific Registry of Transplant Recipients, SRTR KI2019\_01, June 21, 2019, <u>https://optn.transplant.hrsa.gov/media/2985/ki2019\_01\_analysisreport.pdf</u> (accessed December 17, 2019).

#### **Histocompatibility Laboratories**

A 250 NM circle from the transplant program could encompass a longer list of potential candidates than most DSAs, which are currently utilized for reallocation purposes. Histocompatibility laboratories may need to perform additional HLA tests using blood or tissue samples before the organ is reallocated. This may be challenging if the organ has limited samples available for distribution to transplant programs. Histocompatibility laboratories may need to reevaluate practices and thresholds for virtual crossmatching.

### **Potential Fiscal Impact of Proposal**

Implementation of changes to kidney and pancreas reallocation policy may require programming at OPOs, if all elements programmed by the OPTN are not fully supported by local software systems.

Ongoing additional OPO or Transplant center staff time may be significant, depending on change in transplant volume and potential reallocation work. If an organ allocation-sequencing list is re-run, this may result in staff time reviewing the same organ multiple times to determine placement.

Overall transportation costs may also increase for centers, due to potential lost costs in staff time and transport, if organs are not allocated despite attempt. Total average annual cost of transplants determines the annual invoice cost for a regulatory payer, so program and payer costs may change due to any change in organ utility due to reallocation process changes. It may also be challenging for programs to amend existing contracts with non-regulatory (commercial) payers to recover additional costs due to transportation.

However, any staff training at OPOs or Transplant Centers on process changes to implement this proposal can be included in reimbursement requested from payers.

Program size may make cost impact difficult to assess. Large, high volume centers may experience increased volume and staff burden. Small centers can also be affected. While smaller center volume burden may be less, the time burden could be significant with less staff to handle any increased time spent on offers and allocation.

Despite possible impact on OPO and transplant center cost, the potential to place more organs through an efficient process warrant the proposed changes.

### **Post-implementation Monitoring**

#### **Member Compliance**

The proposed language will not change the current routine monitoring of OPTN members. In addition to the monitoring described below, all policy requirements and data entered in UNet<sup>s</sup> may be subject to OPTN review, and members are required to provide documentation as requested.

OPTN staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure allocation was carried out according to OPTN organ specific policies and will continue to examine any allocation deviations. When allocation of an organ does not follow the sequence of the match run, such as bypassing potential transplant recipients (PTR) or accepting for one PTR but transplanting the

organ into another PTR, the OPTN will inquire with the OPO and transplant program, as applicable, for additional information. The MPSC will review all relevant information to determine if a policy noncompliance has occurred and what type of action, if any, is warranted.

#### **Policy Evaluation**

This policy will be formally evaluated approximately 3 months, 6 months, 1 year, and 2 years postimplementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to pre- and post-policy implementation:

- Overall and by OPTN Region:
  - #/% of donors in which an acceptance came from an import match overall and by KDPI
  - #/% of acceptances that came from an import match overall and by KDPI
  - #/% of matches with a bypass code prior to the actual recipient
- For import matches specifically:
  - #/% of kidneys recovered but not utilized (discarded), overall by KDPI
  - #/% and percent kidneys with a final acceptance
  - #/% of matches with a bypass code prior to the actual recipient
  - o Distribution of the number of bypass codes applied for import matches

### Conclusion

Modifications to pancreas and kidney allocation policy to remove DSA and region as distribution units require the modification of reallocation policy as well. The proposed solution provides that the host OPO retain responsibility in managing reallocation of the kidney, pancreas or combined kidney-pancreas. The host OPO would retain the option to continue down the original match run, use a new match run based on a 250 NM circle around the transplant program that originally accepted the organ for one of their patients, or delegate to the OPTN (the Organ Center). This solution keeps responsibility with the OPO most vested in placing the organ and is consistent with the proposed change to removing DSA and region from kidney and pancreas policy, which will promote efficiency in the new allocation system.

The OPO Committee appreciates all feedback related to this proposal, but in particular asks for feedback on the following:

- Do you agree with the host OPO retaining responsibility for reallocation instead of delegating to the OPO in the DSA of the transplant program that originally accepted the organ? If not, please state why.
- Do you agree with a reallocation circle of 250 NM around the transplant program with proximity points inside and outside the circle? If not please state your alternative.
- What operational challenges would the new system incur for you? Specifically, what are the operational challenges related to having new "backup" match runs generated that include offers already screened off?
- In addition to the host OPO being able to continue down the original match run or run a new match run around the transplant program that released the organ, does a third option need to be identified in policy for situations in which it would be appropriate to allow center backup? For example, a high KDPI kidney placed beyond 250 NM.
- Do you have concerns about cross-matching under the proposed solution, or anticipate more use of virtual cross-matching?

• Do you agree it is appropriate having the same solution for kidney and pancreas reallocation?

# OPTN

## **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 5.9 Released Organs

The transplant surgeon or physician responsible for the care of a candidate will make the final decision
 whether to transplant the organ.

4

5 The transplant program must transplant all accepted, deceased donor organs into the original intended

6 recipient or release the deceased donor organs back to and notify the host OPO or the OPTN Contractor

7 for further distribution. If a transplant program released an organ, it must explain to the OPTN

8 Contractor the reason for refusing the organ for that candidate. The host OPO must then allocate the

9 organ to other candidates according to the organ-specific policies. For kidneys, pancreata, and islets, the

10 <u>host OPO may delegate this responsibility to the OPTN Contractor. For all other organs, the host OPO</u>

- may delegate this responsibility to the OPTN Contractor or to the OPO serving the candidate transplant
   program's DSA.
- 13

### 14 8.3 Kidney Allocation Score

15 16

#### Table 8-4: Points for Released Kidneys

#### based on Proximity to Transplant Hospital that Originally Accepted the Organ

- 17 For purposes of this section, distance is calculated in nautical miles between the candidate's hospital of
- 18 registration and the transplant hospital that released the kidney.
- 19

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is 250 nautical miles or less away from the transplant hospital that originally accepted the kidney	$2 - \left[ \left( \frac{2}{250 - 0} \right) \times distance \right]$
Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the transplant hospital that originally accepted the kidney	$4 - \left[ \left( \left( \frac{4}{2500 - 250} \right) \times distance \right) - \left( 4 \times \frac{250}{2500 - 250} \right) \right]$
Registered at a transplant program that is more than 2,500 nautical miles away from the transplant hospital that originally accepted the kidney	<u>0</u>

20

21 22

## 8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

23 Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to

24 20% are allocated to candidates according to *Table 8-6* below. For the purposes of *Table 8-6*,

- 25 distribution will be based on the distance from the candidate's transplant program to the donor
- 26 hospital, unless the kidney is allocated according to Policy 8.8: Allocation of Released Kidneys. For
- 27 kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match
- 28 <u>run, distribution will be based on the distance from the candidate's transplant program to the transplant</u>
- 29 program that released the organ.
- 30 31

#### Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
8	CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
10	CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	0-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
12	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
14	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Nation	Any
15	O-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, top 20% EPTS, and blood type B	250NM	o
17	0-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	Nation	0
18	O-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
19	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	Nation	0

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
20	O-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
21	0-ABDR mismatch, top 20% EPTS, and blood type permissible	250NM	Any
22	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	O-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
24	O-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Nation	Any
25	O-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Top 20% EPTS, blood type B	250NM	A2 or A2B
27	Top 20% EPTS, blood type permissible or identical	250NM	Any
28	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
29	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
30	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
31	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	0
32	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	0
33	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
34	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	250NM	Any
35	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
36	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
37	EPTS greater than 20%, blood type B	250NM	A2 or A2B
38	All remaining candidates, blood type permissible or identical	250NM	Any
39	Registered prior to 18 years old, blood type permissible or identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
40	Top 20% EPTS, blood type B	Nation	A2 or A2B
41	Top 20% EPTS, blood type permissible or identical	Nation	Any
42	All remaining candidates, blood type permissible or identical	Nation	Any

33 34

## 8.5.1 Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-7* below. For the purposes of *Table 8-7*, distribution will be based on the distance from the candidate's transplant program to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match run, distribution will be based on the distance from the candidate's transplant program to the transplant program that released the organ.

## Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the</u> <u>hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	CPRA equal to 98%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
11	0-ABDR mismatch, blood type identical	250NM	Any
12	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
14	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, blood type B	250NM	Ο
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	Ο
18	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	0
19	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	0
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
21	0-ABDR mismatch, blood type permissible	250NM	Any
22	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
25	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Prior liver recipients that meet the qualifying criteria according to <i>Policy</i> 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, blood type permissible or identical	250NM	Any
27	Blood type B	250NM	A2 or A2B
28	All remaining candidates, blood type permissible or identical	250NM	Any
29	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
30	Blood type B	Nation	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the</u> <u>hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
31	All remaining candidates, blood type permissible or identical	Nation	Any

45 46

## 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

47 48 Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-8* below and the following:

49

• Classifications 1 through 29 for one deceased donor kidney

• Classifications 30 and 31 for both kidneys from a single deceased donor

50 For the purposes of *Table 8-8*, distribution will be based on the distance from the candidate's transplant

51 program to the donor hospital, unless the kidney is allocated according to Policy 8.8: Allocation of

52 *Released Kidneys*. For kidneys that are released and the host OPO or the OPTN Contractor executes a

53 released kidney match run, distribution will be based on the distance from the candidate's transplant

- 54 program to the transplant program that released the organ.
- 55

## 56

#### Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
9	CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, blood type identical	250NM	Any
11	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
12	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the</u> <u>hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
15	0-ABDR mismatch, and blood type B	250NM	ο
16	O-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	0
17	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	0
18	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	0
19	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	0
20	0-ABDR mismatch, blood type permissible	250NM	Any
21	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
22	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any
23	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor <u>the</u> <u>hospital that</u> <u>distribution will be based</u> <u>upon</u></del>	With this donor blood type:
24	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
25	Prior liver recipients that meet the qualifying criteria according to Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, blood type permissible or identical	250NM	Any
26	Blood type B	250NM	A2 or A2B
27	All remaining candidates, blood type permissible or identical	250NM	Any
28	Blood type B	Nation	A2 or A2B
29	All remaining candidates, blood type permissible or identical	Nation	Any
30	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
31	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

- 57
- 58 59

#### 8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

- 60 With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than
- 61 85% are allocated to adult candidates according to *Table 8-9* below and the following:

62

- Classifications 1 through 20, 22 and 23 for one deceased donor kidney
- Classifications 21 and 24 for both kidneys from a single deceased donor

For the purposes of *Table 8-9*, distribution will be based on the distance from the candidate's transplant program to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match run, distribution will be based on the distance from the candidate's transplant program to the transplant program that released the organ.

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σ	4

#### Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
6	CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
8	CPRA equal to 98%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
9	0-ABDR mismatch, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
11	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
12	0-ABDR mismatch, blood type B	250NM	Ο
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	Ο
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	Ο
15	0-ABDR mismatch, blood type permissible	250NM	Any
16	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any
17	O-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
18	Prior liver recipients that meet the qualifying criteria according to Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a</del> <del>donor</del> <u>the hospital that</u> <u>distribution will be based</u> <u>upon</u>	With this donor blood type:
19	Blood type B	250NM	A2 or A2B
20	All remaining candidates, blood type permissible or identical	250NM	Any
21	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
22	Blood type B	Nation	A2 or A2B
23	All remaining candidates, blood type permissible or identical	Nation	Any
24	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

#### 66 8.8 Allocation of Released Kidneys

- 67 For kidneys allocated according to *Policy 5.9: Released Organs*, the host OPO may
- 68 1. <u>Continue allocation according to the original match run</u>
- 69 2. Execute a released kidney match run and allocate the kidney using the released kidney match
- 70 run in accordance with *Tables 8-6, 8-7, 8-8, and 8-9*.
- 71 3. <u>Delegate allocation of the kidney to the OPTN Contractor.</u>

#### 72 11.2 Pancreas Allocation Score

- 73Table 11-3: Points for Reallocation of Pancreas, Kidney-Pancreas, and Islets74based on Proximity to Transplant Hospital that Originally Accepted the Organ(s)
- For purposes of this section, distance is calculated in nautical miles between candidate's hospital of
   registration and the transplant hospital that originally accepted the organ(s).

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is 250 nautical miles or less away from the transplant hospital that originally accepted the organ(s)	$2 - \left[\left(\frac{2}{250 - 0}\right) \times distance\right]$
Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the transplant hospital that originally accepted the organ(s)	$4 - \left[ \left( \left( \frac{4}{2500 - 250} \right) \times distance \right) - \left( 4 \times \frac{250}{2500 - 250} \right) \right]$
Registered at a transplant program that is more than 2,500 nautical miles away from the transplant hospital that originally accepted the organ(s)	<u>0</u>

78

## 79**11.4.F**Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To80**30 kg/m²**

81 Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or equal to 30 kg/m<sup>2</sup> will be allocated to candidates according to Table 11-5. For the purposes of Table 11-82 83 5, distribution will be based on the distance from the candidate's transplant program to the donor 84 hospital, unless the kidney-pancreas, pancreas or islets are allocated according to Policy 11.7: Allocation of Released Kidney-Pancreas, Pancreas or Islets. For kidney-pancreas, pancreas or islets that are released 85 86 and the host OPO or the OPTN Contractor executes a released kidney-pancreas match run, distribution 87 will be based on the distance from the candidate's transplant program to the transplant program that released the organ(s). 88

#### 89

#### 90

## Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m<sup>2</sup>

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be</u> <u>based upon</u>
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be</u> <u>based upon</u>
4	Pancreas or kidney-pancreas candidates	250NM
5	Either pancreas or kidney-pancreas candidates, and CPRA greater than or equal to 80%	Nation
6	Pancreas or kidney-pancreas candidates	Nation
7	Islet candidates	250NM
8	Islet candidates	Nation

92 93

## 11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m<sup>2</sup>

94 Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased donors who have a BMI greater than 30 kg/m<sup>2</sup> are allocated to candidates according to Table 11-6 95 96 below. For the purposes of Table 11-6, distribution will be based on the distance from the candidate's 97 transplant program to the donor hospital, unless the kidney-pancreas, pancreas or islets are allocated 98 according to Policy 11.7: Allocation of Released Kidney-Pancreas, Pancreas or Islets. For kidney-pancreas, pancreas or islets that are released and the host OPO or the OPTN Contractor executes a released 99 kidney-pancreas match run, distribution will be based on the distance from the candidate's transplant 100 101 program to the transplant program that released the organ(s). 102

103 104

## Table 11-6: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Oldor with a BMI Greater Than 30 kg/m²

Classification	Candidates that are:	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be based</u> <u>upon</u>
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation
4	Pancreas or kidney-pancreas candidates	250NM
5	Islet candidates	250NM
6	Islet candidates	Nation

Classification	Candidates that are:	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be based</u> <u>upon</u>
7	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	Nation
8	Pancreas or kidney-pancreas candidates	Nation

### **11.7 Allocation of Released Kidney-Pancreas, Pancreas or Islets**

107	<u>For kid</u>	ney-pancreas, pancreas or islets released according to Policy 5.9: Released Organs, the host OPO
108	<u>may</u>	
109	1.	Continue allocation according to the original match run
110	2.	Execute a released kidney-pancreas match run and allocate the kidney-pancreas, pancreas or
111		islets using the released kidney-pancreas match run.
112	3.	Delegate allocation to the OPTN Contractor.
113		
114		#