

Briefing to the OPTN Board of Directors on

Modifications to Released Kidney and Pancreas Allocation

OPTN Organ Procurement Organization Committee

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Modifications to Released Kidney and Pancreas Allocation

<i>Affected Policies:</i>	<p>5.9: Released Organs</p> <p>8.3: Kidney Allocation Score</p> <p>8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%</p> <p>8.5.I Allocations of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less than 35%</p> <p>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%</p> <p>8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</p> <p>8.8 Allocation of Released Kidneys</p> <p>11.4.A: Kidney-Pancreas Allocation Order</p> <p>11.4.C: Organ Offer Limits</p> <p>11.7: Allocation of Released Kidney-Pancreas, Pancreas or Islets</p>
<i>Sponsoring Committee:</i>	Organ Procurement Organization
<i>Public Comment Period:</i>	January 22, 2020 – March 24, 2020
<i>Board of Directors Date:</i>	June 8, 2020

Executive Summary

In December 2019, the OPTN Board of Directors approved the removal of donation service area (DSA) and region from kidney and pancreas allocation policies. These changes require the modification of policies related to the reallocation of released kidneys and pancreata, including *Policy 5.9: Released Organs*. The changes proposed in this briefing paper are intended to provide consistency with the Board-approved changes and promote efficiency and organ utilization.

The OPTN Organ Procurement Organization (OPO) Committee proposes policies addressing the reallocation of kidney, kidney-pancreas, pancreas, and islets in situations in which an organ allocated to an original intended recipient is unable to be transplanted in that recipient.

For released kidneys, the host OPO will have the option to continue allocation using the original match run, contacting the OPTN for assistance, or allocating according to a new released kidney match run.

For released pancreas, kidney-pancreas and islets, the host OPO will have the option to continue allocation using the original match run, contacting the OPTN for assistance, or allocating the organ(s) to a potential transplant recipient at the accepting center. If allocated to a pancreas alone candidate, the kidney must be reallocated according to the released kidney policy.

Background

In December 2019, the OPTN Board of Directors approved the policies that remove DSA and region from kidney and pancreas allocation policy.¹ The Kidney and Pancreas Transplantation Committees did not submit the reallocation or “import backup” solutions to the Board for consideration based on the decision to re-evaluate the reallocation process following mixed public comment feedback, as well as the decision to reduce the original allocation units from 500 to 250 NM.

Currently, OPOs use a practice known as “local backup” to limit preservation time and prevent inefficiencies in organ allocation by providing options regarding what to do with organs that are not transplanted into the original, intended recipient. This process is currently based on DSAs, therefore there is a need to develop kidney and pancreas reallocation policies that are consistent with the Board-approved changes and promotes efficiency and organ utilization. This is particularly true for kidney allocation because of the volume of reallocated kidneys compared to other organs. Relevant reallocation data showed 6,458 (40%) kidney acceptances and 370 (34%) kidney-pancreas/pancreas acceptances were from transplant centers outside the donor recovery DSA. Additionally, 1,683 (10%) kidney acceptances came from a released organ or import (versus host) match run compared to 35 (3%) for kidney-pancreas and pancreas.² This data shows that the scale of reallocation for kidney allocation requires a policy that efficiently addresses the clinical and logistical complexities of this allocation scenario.

Utilization is a concern in the pancreas transplant 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, given the overall decline in pancreas transplantation.³ 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, including transplant center backup.

Purpose

In the absence of policies addressing the reallocation of released organs, 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 traveled a significant distance 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 additional cold ischemic time. This could also increase the chance of organs not being used for transplantation, particularly for pancreata. Patient outcomes and system efficiencies were common themes raised by the transplant community when the proposal to “Eliminate the Use of DSA and Region in Pancreas Allocation Policy” was distributed for public comment in 2019.⁴

¹ Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee, August 2019. https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf. Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee, August 2019.

² Urban, Read. Wilk, Amber. UNOS Research, 2019 OPTN data.

³ Stratta, Robert J., Jonathan A. Fridell, Angelika C. Gruessner, Jon S. Odorico, and Rainer W. Gruessner. Pancreas transplantation: A Decade of Decline. *Current Opinion in Organ Transplantation* 21, no. 4 (August 2016): 386-92. doi:10.1097/mot.0000000000000319.

⁴ Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Pancreas Transplantation Committee, August 2019.

This proposal is intended to provide options for the host OPO when the kidney or kidney-pancreas is released, as outlined in *Policy 5.9: Released Organs*.

The Committee submits the following proposal for the Board consideration under the authority of the Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”⁵

Overall Sentiment from Public Comment

This proposal was released for public comment from January 22, 2020 to March 24, 2020. The proposal included a released match run for kidney, pancreas, and kidney-pancreas. This proposal was generally supported during public comment with several themes making up a majority of the comments. These comments were the focus of the Committee’s post-public comment changes:

- Concern about reallocating the pancreas using the same process as kidney reallocation
- Support for a smaller reallocation circle or center backup for pancreata

Additional comments were received on the themes listed below. While these valuable comments did not result in proposed policy changes, they could lead to future work that could prove valuable to the transplant community.

- *Host OPO retaining responsibility for the reallocation of released organs* - Most of the comments on this issue were in support since the intent is to avoid inefficiencies and added complexity. Since there were significantly more comments in support, the Committee is not proposing changes to the language.
- *Cross matching* – Several regions and professional organizations expressed concern about the availability of crossmatching materials. This issue continues to come up as a concern related to broader distribution. Similar comments were provided on the Kidney Transplantation Committee’s proposal to remove DSA and region.⁶ No proposed changes were made based on these comments; however, the Committee agrees that this issue needs to be addressed through the policy development process.

As shown in **Figure 1**, a total of 217 sentiment votes were submitted as part of the eleven regional meetings. The Region 9, 10, and 11 meetings were held virtually due to the COVID-19 crisis. The proposal was supported in all eleven regions with Region 5 approving the proposal with the provision to allow host OPO to delegate allocation to the receiving center’s OPO. Approximately 75% of the votes were in support of the proposal.

Briefing paper to the Board of Directors. https://optn.transplant.hrsa.gov/media/3370/eliminate-the-use-of-dsas-and-regions-in-pancreas-allocation_112219.pdf

⁵ 42 CFR §121.4(a)

⁶ Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee, August, 2019. Briefing paper to the Board of Directors. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf

Figure 1: Sentiment Votes, by Region⁷

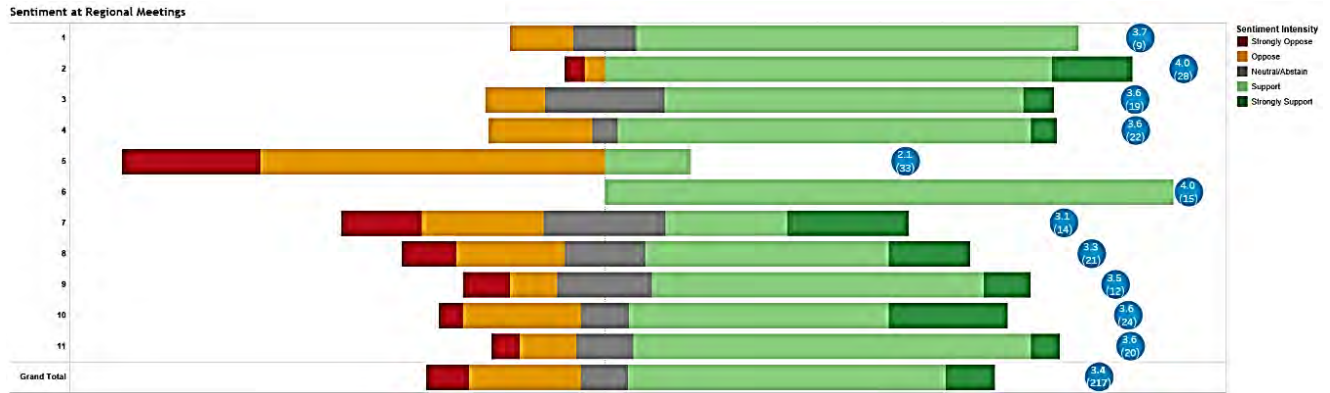
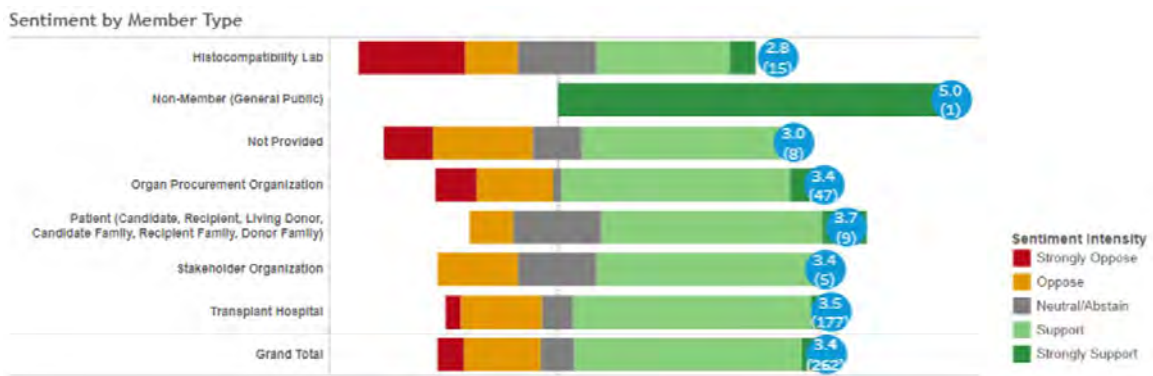


Figure 2 illustrates sentiment support by OPTN member type. There was significant support for the proposal across all member types with similar scores from both OPOs and transplant centers.

Figure 2: Sentiment Votes, by Member Type⁸



All the OPTN Committees that reviewed the proposal were supportive, although there were concerns raised about the pancreas reallocation solution. The Membership and Professional Standards Committee (MPSC) took two separate votes, one in support of the kidney reallocation solution and the other against the pancreas reallocation solution. Similar to many of the comments, the main concern was the impact of increased cold ischemia time on the pancreas. The MPSC also did not support the requirement for the host OPO responsibility for reallocation, especially in cases where the organ(s) have traveled a significant distance. However, the Transplant Coordinators and Operations and Safety Committees both supported this requirement.

The following professional organizations provided feedback on the proposal:

⁷ 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.

⁸ 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

- American Society of Transplantation (AST)
- Association Society of Transplant Surgeons (ASTS)
- The Organization for Transplant Professionals (NATCO)
- Association of Organ Procurement Organizations (AOPO)
- American Nephrology Nurses Association (ANNA).

Most of the organizations were generally supportive of proposals that minimize unnecessary non-utilization of organs. Each organization raised concerns about the reallocation of the pancreas. The ASTS did not support the proposal as written and proposed a framework where any organ placed within 250 NM would be reallocated according to the original match run. Organs placed outside the 250 NM could be placed using a variety of options including a 150 NM circle, delegating to the accepting transplant center’s OPO, Organ Center expedited placement, and transplant center backup.

Proposal for Board Consideration

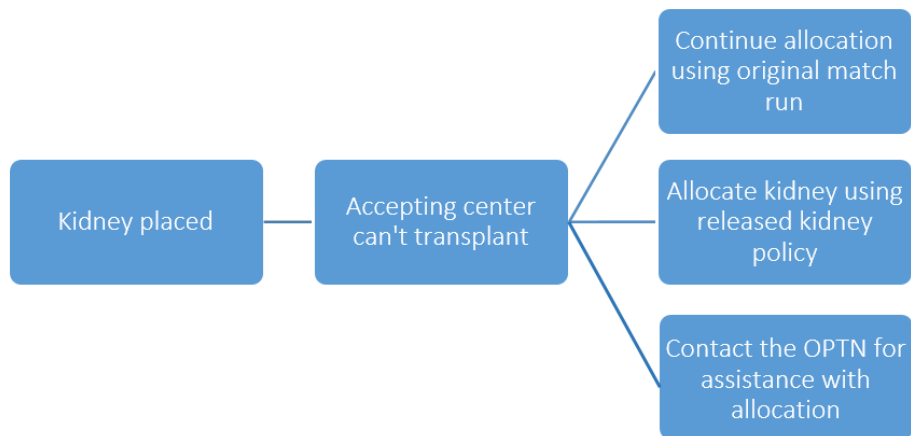
This proposal contains the following components for Board consideration:

Kidney Reallocation

Policy 5.9: Released Organs states that the host OPO must allocate released organs according to organ-specific policies or delegate the responsibility to the OPTN or OPO serving the candidate transplant program’s DSA. This proposal removes the option to delegate allocation of released kidneys to the OPO serving the original accepting transplant center’s OPO. The host OPO may continue allocation according to the original match run, contact the OPTN for assistance with allocation, or allocate the kidney using the released kidney match run. This solution was well supported by the community.

Figure 3 illustrates the proposed process for allocating released kidneys.

Figure 3: Allocation of Released Kidneys



Notification of Released Organs

Policy 5.9: Released Organs includes a requirement that transplant programs that do not transplant accepted deceased donor organs into the original intended recipient release the “organs back to and notify the host OPO or the OPTN Contractor for further distribution.” Several comments, including those

from AOPO, request that policy language specify this notification be “immediate” in order for the host OPO to initiate reallocation. This will allow OPOs to initiate reallocation sooner to avoid additional cold ischemia time. Therefore, modifications to Policy 5.9: Released Organs include a new requirement that the transplant program releasing the organ to “immediately notify the host OPO or the OPTN for further distribution.”

Host OPO Responsibility

The Committee believes that the host OPO retaining responsibility for reallocation avoids delays and logistical challenges that are encountered by delegating allocation to another OPO when an organ allocated to an original intended recipient is unable to be transplanted in that recipient. Of the twelve public comments specifically mentioning this aspect of the proposal, ten were in support, including comments from AST, ASTS, and NATCO. AOPO agreed with the Committee’s rationale for requiring the host OPO retain responsibility for reallocation but also supported additional options, including the use of the Organ Center and the OPO closer to the accepting center, to assist with more efficient placement. Region 5 and the MPSC did not support this requirement because if the organ(s) have traveled a significant distance, the host OPO could be working with unfamiliar transplant centers. However, the Committee agreed that the host OPO has the vested interest in placing the organ(s) and is aware of the organ quality and the donor management history.

Kidney-Pancreas and Pancreas Reallocation

After consideration of public comments, the Committee is proposing revisions to the process for the reallocation of released kidney-pancreas and pancreas. The main concern raised during public comment was the allocation of released pancreata using the same solution as released kidneys. There were recommendations to consider a smaller reallocation circle (e.g. 150 NM) or allow for transplant center backup of the pancreas. However, the Committee acknowledged that a smaller reallocation circle would not address the concerns about cold ischemia time and did not move forward with that option.

Numerous public comments noted that additional time spent trying to reallocate a released pancreas or kidney-pancreas increases cold ischemia time and puts the organs at risk of not be used for transplant and has a negative impact on outcomes. In 2017, research by Rudolph et al “sought to systematically assess the impact of cold ischemia time (CIT) on outcomes post-transplant” for pancreas after kidney, simultaneous pancreas and kidney, and pancreas transplants. They concluded “long-term graft survival was best with less than 12 hours of CIT; graft failure increased 1.2-fold to 1.4-fold with 12-24 hours of CIT and 2.2-fold with more than 24 hours of CIT.”⁹ Cold ischemia time can also affect kidneys, although Dube et al concluded that while “the prevalence of kidney transplants from donors with acute kidney injury and prolonged CIT is increasing, and transplants from these donors result in excellent long-term clinical outcomes, with 3-year graft survival rates similar to those reported among all deceased donor renal transplant recipients in the U.S.”¹⁰

Initial post public comment discussions focused on allowing the accepting transplant program to place the pancreas alone with a candidate at their program in order to avoid additional cold ischemia time. However, since most pancreata are allocated as part of a kidney-pancreas combination, further

⁹ 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

¹⁰ Dube, G.K., Brennan, C., Husain, S.A., Crew, R.J., Chiles, M.C., Cohen, D.J. and Mohan, S. (2019), Outcomes of kidney transplant from deceased donors with acute kidney injury and prolonged cold ischemia time – a retrospective cohort study. *Transplant International*, 32: 646-657. doi:[10.1111/tri.13406](https://doi.org/10.1111/tri.13406)

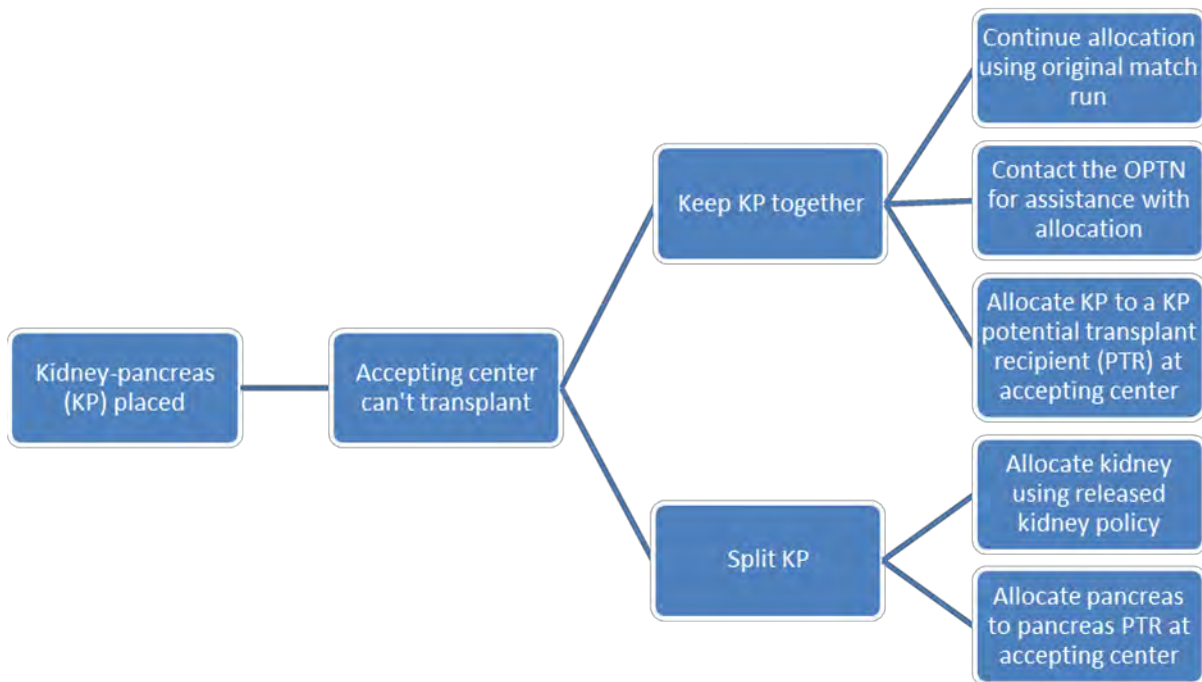
discussions focused on allowing the accepting transplant program to place the organs with a kidney-pancreas candidate at their center.¹¹ The leadership of the Kidney and Pancreas Transplantation Committees supported not forcing the separation of the kidney and pancreas if there was an appropriate potential transplant recipient at the accepting transplant center. Finally, they supported the requirement to reallocate the kidney if the pancreas alone is placed at the original accepting center. This allows additional access to offers for those candidates on the kidney match run.

The Committee is proposing that when a kidney-pancreas, pancreas or islets are released according to *Policy 5.9: Released Organs*, the following options are available to the host OPO:

1. Continue to allocate according to the original match run
2. Contact the OPTN for assistance with allocation
3. Allocate the kidney-pancreas, pancreas or islets to a potential transplant recipient at the transplant program that originally accepted the organ. If allocating to a pancreas alone potential transplant recipient at the same program, the kidney must be allocated according to *Policy 8.8: Allocation of Released Kidneys*.

Figure 4 illustrates the proposed process for allocating released pancreas and kidney-pancreas.

Figure 4: Allocation of Released Pancreas and Kidney-Pancreas



Additional Policy Changes

There are several additional policy language changes highlighted below:

- Replaced “the OPTN Contractor” with “the OPTN” from *Policy 5.9: Released Organs* in order to be consistent with other policies.

¹¹ 2019 OPTN data (accessed April 28, 2020). 143 pancreas transplants, 873 kidney-pancreas transplants.

- *11.4.A: Kidney-Pancreas Allocation Order and 11.4.C: Organ Offer Limits* – Policy language was added to specify that these sections do not apply to released organs in order to prevent conflicts between the proposed language and current policy.

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**¹² of OPO professionals, transplant surgeons, and members of four stakeholder committees in deriving the proposed changes. These experts used their collective experience to determine the best approach to address the allocation of released organs. They considered such factors as distance, cold ischemia time, and logistics in order to identify the best solutions for efficiently allocating released organs.
- **Is designed to avoid wasting organs**¹³ by ensuring alternative allocation is available for organs that may otherwise not be utilized when ischemic time and organ quality affect availability and utilization opportunities. As noted previously, 6,458 (40%) of kidney acceptances and 370 (34%) of kidney-pancreas/pancreas acceptances were from transplant centers outside the donor recovery DSA, with 1,683 kidney acceptances from a released organ match run.
- **Promotes the efficient management of organ placement**¹⁴ by allowing the host OPO to run a released kidney match around the transplant program that accepted but can no longer use the organ or place the pancreas, kidney-pancreas, and islets with a potential transplant recipient at the original accepting center, thus avoiding additional costs of sending the organ elsewhere, or the time and resources it would take to otherwise re-allocate the organ.
- **Is not based on the candidate's place of residence or place of listing, except to the extent required**¹⁵ to avoid wasting organs, by allowing organs that have already accrued cold ischemic time to be placed more rapidly, and promoting the efficient management of organ placement by avoiding the additional resources and time associated with re-allocation down the original list, as noted previously.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,¹⁶ and it is specific to an organ type, in this case kidneys, pancreata, and islets.¹⁷

¹² 42 CFR §121.8(a)(1).

¹³ 42 CFR §121.8(a)(5).

¹⁴ 42 CFR §121.8(a)(5).

¹⁵ 42 CFR §121.8(a)(8).

¹⁶ 42 CFR §121.8(a)(3).

¹⁷ 42 CFR §121.8(a)(4).

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:

- Shall seek to achieve the best use of donated organs
- Shall be designed to avoid futile transplants
- Shall be designed to promote patient access to transplantation

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.¹⁸ The Committee did not identify any populations that may be treated “less favorably than they would have been treated under the previous policies” if these proposed policies are approved by the Board of Directors, and does not recommend that the Board adopt any particular transition procedures.

Alignment with OPTN Strategic Plan¹⁹

Promote the efficient management of the OPTN: This proposal promotes the efficient management of the OPTN by establishing an efficient process for reallocating organs that can no longer be used by the originally intended candidate.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

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 continuing to build new relationships with transplant programs outside the OPO’s DSA. Additional staff or staff hours may be necessary, dependent on change on 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 crossmatching; if of 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.

Operations affecting Transplant Hospitals

Transplant programs may be impacted because of limited donor blood or tissue samples, which may inhibit some programs from performing testing for their potential candidates. In practice, transplant programs may need to adjust 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. Transplant programs may also increase utilization of virtual crossmatching to mitigate the effect of the policy change.

Operations affecting Histocompatibility Laboratories

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

¹⁸ 42 CFR §121.8(d).

¹⁹ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

distribution to transplant programs. Histocompatibility laboratories may need to reevaluate practices and thresholds for virtual crossmatching.

Operations affecting the OPTN

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 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. For combined kidney-pancreas & pancreas allocation, host OPOs will have the option to continue allocation on the original match run, contact the Organ Center for assistance, or place the organ(s) with a potential transplant recipient at the accepting center. This post public comment change will not increase the level of effort for the programming changes that will be released with the project to remove DSA and region from kidney-pancreas and pancreas allocation.

The OPTN will follow established protocols to inform members of any policy changes through Policy Notices. The OPTN will also create educational materials for the allocation of released kidneys and pancreata. Education will coincide with implementation.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

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

Projected Impact on Organ Procurement Organizations

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 the 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.

Projected Impact on Transplant Hospitals

Overall transportation costs may also increase for centers, due to potential lost costs in staff time and transport, if reallocated organs are not placed despite allocation attempts. 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 transplant programs to amend existing contracts with non-regulatory (commercial) payers to recover additional costs due to transportation.

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.

Projected Impact on the OPTN

Significant Policy and Community Relations and IT hours, in a condensed amount of time, resulted in a reallocation solution that aligns with the newly approved kidney and pancreas allocation systems.

A large IT implementation effort, estimated at 1,560 hours, includes a four-person team over an anticipated three-month programming period. Professional Education anticipates a small effort in creating an instructional offering.

Approximately 100 hours per year of ongoing monitoring from the Research Department is anticipated, and will monitor Potential Transplant Recipient (PTR) data.

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.”²⁰

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 UNetSM 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 review any allocation deviations. OPTN staff will inquire with OPOs and transplant programs, as applicable, for additional information when a deviation is identified. 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

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”²¹

This policy will be formally evaluated approximately 3 months, 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 plus days to be submitted)) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy:

For Kidney, Kidney-Pancreas, and Pancreas Donors/Organs:

- Overall and by OPTN Region (and KDPI if KI or KP)
 - N/% of organs with a final acceptance
 - N/% of organs for which an acceptance came from an import match run
 - N/% of kidneys for which an acceptance came from a released match run (KI only)
- For accepted organs
 - N/% with the following outcomes:
 - Transplanted with the accepting candidate
 - Transplanted with a different candidate at the accepting center
 - Transplanted at a different center
 - Discarded
 - Stratify by:
 - OPTN Region
 - Donor KDPI (for KI and KP)
 - Accepting patient CPRA (for KI and KP)

²⁰ 42 CFR §121.8(a)(7)

²¹ 42 CFR §121.8(a)(6)

Conclusion

Modifications to pancreas and kidney allocation policy to remove DSA and region as distribution units require modifications to policies addressing released organs. For the reallocation of kidneys, the host OPO would retain the option to continue allocation using the original match run, execute 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 contact the OPTN (the Organ Center) for assistance.

For the reallocation of kidney-pancreas and pancreas, the host OPO would retain the option to continue allocation using the original match run or contact the OPTN for assistance with allocation. Additionally, this proposal includes an additional option of allowing the host OPO to allocate the kidney-pancreas or pancreas to a potential transplant recipient at the originally accepting transplant program. If the pancreas alone is allocated to a potential transplant recipient at the program, the kidney alone must be reallocated according to policy.

Finally, this solution keeps the reallocation responsibility with the host OPO. The host OPO has a vested interest in placing the organ and the historical knowledge about the organ quality and donor management.

This proposal addresses the requirements in NOTA and the Final Rule by using medical judgment to avoid organs not being used for transplant and to improve the efficiency of organ placement.

Policy Language

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

2 The transplant surgeon or physician responsible for the care of a candidate will make the final decision
3 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 immediately notify the host OPO or the
7 OPTN ~~Contractor~~ for further distribution. If a transplant program released an organ, it must explain to
8 the OPTN ~~Contractor~~ the reason for refusing the organ for that candidate. The host OPO or OPTN must
9 then allocate the organ to other candidates according to the organ-specific policies. ~~The host OPO may~~
10 ~~delegate this responsibility to the OPTN or to the OPO serving the candidate transplant program's DSA.~~
11 The host OPO may contact the OPTN for assistance allocating the organs. The host OPO may delegate
12 this responsibility to the OPO serving the candidate transplant program's DSA, except in the cases of
13 released kidneys, pancreata, and islets.
14

15 8.3 Kidney Allocation Score

16 **Table 8-4: Points for Released Kidneys**
17 **based on Proximity to Transplant Hospital that Originally Accepted the Organ**

18 For purposes of this section, distance is calculated in nautical miles between the candidate's hospital of
19 registration and the transplant hospital that released the kidney.
20

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

22 **8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or**
 23 **equal to 20%**

24 Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to
 25 20% are allocated to candidates according to *Table 8-6* below. For the purposes of *Table 8-6*,
 26 distribution will be based on the distance from the candidate’s transplant hospital to the donor hospital,
 27 unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are
 28 released and the host OPO or the OPTN executes a released kidney match run, distribution will be based
 29 on the distance from the candidate’s transplant hospital to the transplant hospital that released the
 30 organ.

31
 32 **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 <u>at or within this distance from a donor the hospital that distribution will be based 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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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
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	0-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	O

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
18	0-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	O
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	O
20	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
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	0-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	0-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	0-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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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
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	O
32	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	O
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	O
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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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
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

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8.5.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

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

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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 <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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
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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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	O
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	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	O
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	O
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , 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
31	All remaining candidates, blood type permissible or identical	Nation	Any

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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%

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:

50

- Classifications 1 through 29 for one deceased donor kidney
- Classifications 30 and 31 for both kidneys from a single deceased donor

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

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%**

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Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based 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	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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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
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	O
16	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
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	O

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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	O
19	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
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
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 <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
26	Blood type B	250NM	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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

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

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

62

63

- 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 hospital 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 executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

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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 <u>at or within this distance from a donor the hospital that distribution will be based 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
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

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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	O
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
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	0-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 <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
19	Blood type B	250NM	A2 or A2B
20	All remaining candidates, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is <u>at or within this distance from a donor the hospital that distribution will be based upon</u>	With this donor blood type:
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

67 **8.8 Allocation of Released Kidneys**

68 For kidneys allocated according to *Policy 5.9: Released Organs*, the host OPO may

- 69 1. Continue allocation according to the original match run
- 70 2. Allocate the kidney using the released kidney match run in accordance with *Tables 8-6, 8-7, 8-8, and*
- 71 *8-9* or
- 72 3. Contact the OPTN for assistance allocating the kidney

73

74 **11.4.A Kidney-Pancreas Allocation Order**

75 If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO must
76 offer the kidney and pancreas in the following order:

- 77 1. The host OPO must offer the kidney and pancreas according to classifications 1–5 in
78 *Tables 11-4: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and*
79 *Less with a BMI less than or equal to 30 kg/m² and 11-5: Allocation of Kidneys and*
80 *Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m².*
- 81 2. Then, the host OPO may do either:
82 a. Continue to offer the kidney and pancreas according to the remaining classifications
83 in *Table 11-4*.
84 b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas
85 candidates, according to the remaining classifications *Table 11-4* and offer the
86 kidney to kidney candidates according to *Policy 8: Allocation of Kidneys*.

87 The host OPO may switch between options 2.a and 2.b above at any time after completing step
88 1 above.

89 This subsection does not apply if the kidney and pancreas have been released according to
 90 Policy 5.9: Released Organs.

91
 92 **11.4.C Organ Offer Limits**

93 Any pancreas that will be shared as zero antigen mismatches, either alone or in combination
 94 with kidneys, must be offered within eight hours after procurement.

95
 96 If there are at least 10 zero antigen mismatched potential recipients on the match run, the
 97 pancreas must be offered to the first 10 zero antigen mismatched potential recipients. If there
 98 are less than 10 zero antigen mismatched potential recipients, the pancreas must be offered to
 99 all zero antigen mismatched potential recipients.

100 If these offers are not accepted then the Host OPO must:

- 101 • Allocate the organ according to the match run under *Policy 8.5: Kidney Allocation*
 102 *Classifications and Rankings* and allocate the pancreas according to *Policy 11.4: Pancreas,*
 103 *Kidney-Pancreas, and Islet Allocation Classifications and Rankings.*
- 104 • Allocate the organ for the remaining zero antigen mismatched potential recipients.

105
 106 This subsection does not apply if the pancreas has been released according to Policy 5.9:
 107 Released Organs.

108
 109 **11.7 Allocation of Released Kidney-Pancreas, Pancreas or Islets**

110 For kidney-pancreas, pancreas or islets released according to Policy 5.9: Released Organs, the host OPO
 111 may

- 112 1. Continue allocation according to the original match run
- 113 2. Allocate the kidney-pancreas, pancreas or islets to a potential transplant recipient at the
 114 transplant program that originally accepted the organ(s). If allocating to a pancreas alone
 115 potential transplant recipient at the same program, the kidney must be allocated according to
 116 Policy 8.8: Allocation of Released Kidneys or
- 117 3. Contact the OPTN for assistance allocating the organ(s)

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