OPTN | UNOS Public Comment Proposal

OPTN/UNOS Kidney Transplantation Committee

Kidney Allocation System (KAS) Clarifications & Clean Up

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Kidney Allocation System (KAS) Clarifications & Clean Up

Executive Summary

The OPTN implemented the revised kidney allocation system (KAS) on December 4, 2014. Since the OPTN/UNOS Board of Directors approved the policy in June 2013, the Kidney Transplantation Committee (the Committee) and UNOS staff have identified areas in which changes and clarifications are needed in the policy language. This proposal focuses on five areas for changes to kidney allocation policy:

1. Removing policy on mandatory sharing
2. Clarifying informed consent requirements for multi-organ candidates for kidneys based on KDPI greater than 85%
3. Maintaining consistency throughout kidney allocation policy with regard to *Policy 5.9: Released Organs*
4. Correcting match classification language in *Table 8-5: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal to 20%*
5. Clerical changes

The Committee believes that the changes outlined in this proposal will provide clarification on kidney allocation policy and increase equitable access to very highly sensitized candidates. Other clarifications will improve the overall efficiency of KAS.

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

Readers may comment on the entire proposal, but the Committee would like specific feedback on *Policy 5.3.C: Informed Consent for Kidneys Based on KDPI Greater than 85% and Policy 8.5.C: Informed Consent for Kidneys Based on KDPI Greater than 85%*. These policies require that, prior to receiving offers for kidneys with a KDPI score greater than 85%, transplant programs obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category. The Committee would like to know:

1. Should the requirement for written, informed consent apply to multi-organ candidates that are registered for a kidney and another organ?
2. If this requirement does apply to multi-organ candidates, should consent be obtained prior to receiving offers? Or, should consent be obtained prior to transplant?

Kidney Allocation System (KAS) Clarifications & Clean Up

Affected Policies: Policy 5.3.C: Informed Consent for Kidneys, Policy 8.2.B:Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings, Policy 8.5.C: Informed Consent for Kidneys Based on KDPI Greater than 85%, Policy 8.5.E: Allocation of Kidneys by Blood Type, Policy 8.5.G: Highly Sensitized Candidates, Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, Policy 8.6: Double Kidney Allocation, Policy 8.7.A: Mandatory Sharing, Policy 8.7.B Choice of Right versus Left Donor Kidney, Policy 8.7.C: National Kidney Offers, Policy 8.7.D: Kidney-Non-renal Organs Allocated and Not Transplanted

Sponsoring Committee: Kidney Transplantation Committee

Public Comment Period: January 25 – March 25, 2016

What problem will this proposal solve?

The OPTN implemented the revised kidney allocation system (KAS) on December 4, 2014. Since the OPTN/UNOS Board of Directors approved the policy in June 2013, the Kidney Transplantation Committee (the Committee) and UNOS staff have identified clarifications that are needed in the policy language. The Committee believes it is important to address these clarifications in order to ensure maximum efficiency and equity in access to KAS. This proposal focuses on five areas for changes to kidney allocation policy:

1. Removing policy on mandatory sharing
2. Clarifying informed consent requirements for multi-organ candidates for kidneys based on KDPI greater than 85%
3. Maintaining consistency throughout kidney allocation policy with regard to *Policy 5.9: Released Organs*
4. Correcting match classification language in *Table 8-5: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%*
5. Clerical changes

1. Mandatory Sharing

Mandatory sharing policy refers to the number of match offers and time limits for making offers to candidates that are 0-ABDR mismatches and 99%-100% CPRA candidates who are eligible for regional and national priority[1]. For deceased donor kidneys with a KDPI less than or equal to 85%, the Organ Procurement Organization (OPO) must make at least 10 offers within 8 hours of procurement. For deceased donor kidneys with a KDPI greater than 85%, the OPO must make at least 5 offers within 3 hours of procurement. While this policy outlines the number of mandatory share offers an OPO must make within a certain time period, it does not specify what OPOs can or must do after making the minimum number of offers if the offers are not accepted.

[1] Candidates with 99-100% CPRA are in match classifications 1-10 of each allocation sequence. In order for a candidate with a CPRA score of 99% or 100% to be eligible for regional and national priority in these match classifications, the transplant program's HLA laboratory director and the candidate's transplant physician or surgeon must review and sign a written approval of the unacceptable antigens listed for the candidate.

Under current practice, some OPOs make the minimum number of mandatory share offers, and after that number is reached, use a bypass code to skip the remaining 99-100% CPRA and 0-ABDR mismatches and begin making local offers. This means that an OPO can potentially skip a very highly sensitized candidate with a 99% or 100% CPRA who appears after the 10th or 5th potential transplant recipient on the match run in favor of offering the kidney to a local candidate.

The Committee recommends removing the mandatory sharing policy and inactivating the bypass code so that OPOs must make offers according to the match run. This change will ensure that OPOs continue making offers in cases where more than 10 or 5 very highly sensitized candidates appear on the match run. OPOs can still use other currently available bypass codes (e.g. expedited placement, donor medical urgency, etc.) to skip candidates on the match run, but the OPO must report to the OPTN a reason for using these codes. UNOS allocation analysts review the match runs on a rolling basis and the Membership and Professional Standards Committee (MPSC) may review these cases for potential violations.

2. Informed Consent for Multi-Organ Candidates for Kidneys Based on KDPI Greater than 85%

Kidney policy on informed consent requires that transplant programs obtain written, informed consent from each kidney candidate willing to receive offers for kidneys with a KDPI score greater than 85%. Because the policy does not specifically exclude multi-organ candidates, UNOS staff have interpreted that this requirement also extends to candidates that are listed for both a kidney and another organ. Clarification is needed as to whether explicit consent for receiving KDPI>85% kidney offers is required for multi-organ candidates, since allocation of the kidney to these patients is based on allocation of the other organ (liver, pancreas, heart, or lung), not the kidney-alone match run.

The Committee was divided on this clarification. Ultimately, Committee members compromised by initially adding clarification to the policy that this requirement applies to multi-organ candidates while requesting specific public comment feedback on this topic (see: Is the sponsoring Committee requesting specific feedback or input about the proposal?). The Committee would like to know (1) if the transplant community believes requiring written, informed consent to receive offers for kidneys with a KDPI score greater than 85% should apply to multi-organ candidates and (2) if so, should consent be obtained prior to receiving offers or prior to transplant.

3. Maintain Consistency with Released Organ Policy

If deceased donor organs cannot be transplanted into the originally intended recipient, *Policy 5.9: Released Organs* requires the transplant program to release the organs back to the host OPO and notify the host OPO or the OPTN Contractor for further allocation. The host OPO must allocate the organ to other candidates according to the organ-specific policies (i.e., according to a match run), or can opt to let the OPTN Contractor or the OPO serving the candidate transplant program's designated service area (i.e. the "importing OPO") allocate the organ instead.[2] This policy applies to all organ allocation; however, UNOS staff identified three instances in *Policy 8: Allocation of Kidneys* that conflict with *Policy 5.9*. These instances are described below.

Policy 8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings: Currently, deceased donor kidneys are allocated based on the donor histocompatibility laboratory's HLA typing. However, the recipient's HLA laboratory must retype the donor to confirm the HLA type. If the recipient HLA laboratory identifies a different HLA type (i.e. a discrepancy), this policy permits either the

[2] The MPSC is considering a separate project that may revise *Policy 5.9: Released Organs*. The MPSC believes that there is confusion and variability in how members reallocate organs when an organ cannot be transplanted into its originally intended recipient. This proposal only seeks to alleviate further confusion between *Policy 5.9: Released Organs* and *Policy 8: Allocation of Kidneys*, and does not address "local back-up" organ allocation.

kidney to be allocated according to the original HLA typing, *or* the recipient transplant hospital may reallocate the kidney locally. This policy may be ambiguous because it does not clearly state who decides which HLA typing to use and permits a recipient transplant hospital to reallocate the kidney rather than an OPO. The proposed revision is that *Policy 5.9* will be the prevailing policy if the discrepancy cannot be resolved and the intended recipient cannot be transplanted. The OPO will have the discretion to allocate the organ based on the original donor lab HLA typing <u>or</u> the recipient lab HLA typing. The proposed language does not direct which HLA typing must be used because there may be unknown consequences for patient safety by requiring that the donor lab HLA typing be always be used instead of the recipient lab HLA typing or vice versa.

Policy 8.7.C National Kidney Offers: This policy describes when the OPO must contact the Organ Center to assist with national placement of kidney offers. This proposal removes language in *Policy 8.7.C* stating that the importing OPO must select alternate candidates if the kidney cannot be transplanted into the original intended candidate. Removing this language makes *Policy 5.9: Released Organs* the prevailing policy and allows an importing OPO to select an alternative candidate only if the host OPO has delegated responsibility for reallocation to the importing OPO. Reallocation of the kidney to other candidates would still be according to the kidney allocation policies whether it was allocated by the host OPO, the importing OPO, or the Organ Center. This section also contains clerical changes to clarify existing policy.

Policy 8.7.D Kidney-Non-renal Organs Allocated and Not Transplanted: Currently, if a kidney is allocated as part of an accepted multi-organ combination offer that does not result in a transplant, it must immediately be offered to 0-ABDR mismatch candidates. However, very highly sensitized candidates (i.e. CPRA ≥ 98%) now appear before 0-ABDR mismatch candidates in the revised KAS sequences. This requirement existed in policy before KAS was implemented, when 0-ABDR mismatches were at the top of the kidney allocation sequences, and requires an update to reflect the current allocation sequences. The proposed language specifies that OPOs must reallocate kidneys that are not transplanted in multi-organ combinations according to *Policy 5.9: Released Organs*, which requires that the organ be allocated to other candidates according to the organ-specific policies (i.e. *Policy 8: Allocation of Kidneys)*.

4. Correct Match Classification Language

Table 8-5 describes the order of allocation for offers from deceased donors with a KDPI less than or equal to 20%. During the programming phase of KAS, UNOS staff identified match classifications that needed corrections in *Table 8-5*. **Table 1** below provides an example:

Table 1: Match Classification Example from *Table 8-5*

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
16	OPO's region	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	Any
20	OPO's region	0-ABDR mismatch, top 20% EPTS **or 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 identical	Any

These two classifications are identical with the exception that classification 20 allows the candidate to be either in the top 20% EPTS *or* less than 18 years old at the time of the match run. However, if the candidate was less than 18 at the time of the match run, the candidate would have already qualified for classification 16.

KAS was programmed so that these pediatric candidates already fall into the more advantageous match classification, but the policy language should be corrected to remove the inadvertent duplication. This proposal would correct the allocation table in policy by removing "or less than 18 years old at time of match run" and also change the classification titles in UNet[SM].[3]

5. Clerical Changes

UNOS staff also identified references to the allocation sequences throughout *Policy 8* that need updating. For example, *Policy 8.5.G: Highly Sensitized Candidates* requires a written approval from the HLA laboratory director and the candidate's physician or surgeon of the unacceptable antigens for candidates with a CPRA greater than 98% to receive regional and national sharing priority. However, the policy currently only requires this approval for allocation of kidneys with a KDPI greater than 20% but less than 35% (*Table 8-6*), rather than applying to every allocation sequence. Additionally, *Policy 8.6: Double Kidney Allocation* limits double kidney allocation to kidneys with KDPI less than or equal to 20% or greater than 85%, but not the allocation sequences in between. These omissions were clerical and the policies will be updated to apply to all allocation sequences.

Why should you support this proposal?

The Committee believes that the changes outlined in this proposal will clarify kidney allocation policy and provide more equitable access for highly sensitized candidates. Other clarifications will improve the overall efficiency of KAS.

How was this proposal developed?

The proposal was developed through a KAS Post-Implementation Subcommittee (Subcommittee) tasked with reviewing data trends, assessing the need for post-implementation policy clarifications, and determining the need for IT programming changes. The Subcommittee includes representatives from the Kidney, OPO, Histocompatibility, Minority Affairs, and the Transplant Administrators Committees. Based on feedback from the transplant community and issues identified by UNOS staff, the Subcommittee made several recommendations to the Committee for policy clarifications.

The Committee agreed with the Subcommittee's recommendations on maintaining consistency with released organ policy, correcting match classification language, and clerical changes (all described above in "What problem will this proposal solve?"). The Committee did not fully agree with the Subcommittee's initial recommendations on the mandatory sharing policy and informed consent requirements.

Mandatory Sharing

Prior to KAS implementation, mandatory sharing only applied to 0-ABDR mismatch candidates, who appeared at the top of the allocation sequences. After the minimum number of offers were made but turned down, the host OPO could either offer the organ to the remaining 0-ABDR mismatch potential recipients *or* offer it according to the kidney and kidney-pancreas policy. The bypass code allowed the OPOs to make offers to potential recipients beyond the remaining 0-ABDR mismatches after making the minimum number of required offers. After KAS implementation, the bypass code remained active and

[3] This change would be made to classifications 20, 21, 29, 38, and 39 in *Table 8-5*.

current policy does not specify what OPOs can or must do after making the minimum number of offers if they are not accepted.

In October 2015, the Subcommittee recommended updating the policy on mandatory sharing to reflect the current practice. The Committee disagreed because very highly sensitized candidates now appear at the top of the allocation sequences ahead of 0-ABDR mismatches. Very highly sensitized candidates (i.e. CPRA 99-100%) may only be compatible with 1% or less of all donors, which means longer waiting time and higher rates of death on the waiting list for these candidates.

In the first six months of KAS, 22 OPOs bypassed a potential transplant recipient and did not offer the kidney because the minimum offers required by the mandatory sharing policy was met. These OPOs used the bypass code:

- 902 times for 51 donors, which represents 1.3% of all recovered kidney donors (for 3 donors, the code was reported more than 50 times for each of the donors)
- 53% of candidates bypassed were non-local, CPRA 99-100%
- 47% of candidates bypassed were other 0-ABDR mismatches

One of the main goals of KAS was to increase equity in access for highly sensitized candidates. The Committee believes that if the match run identifies a compatible deceased donor kidney for a very highly sensitized candidate it should be offered due to the limited opportunities for these candidates to receive an organ offer. Additionally, Committee members were concerned that very highly sensitized candidates may not be treated equitably across the country because some OPOs use the local bypass code to place kidneys after meeting the mandatory sharing requirements while others do not.

In November 2015, the Subcommittee considered two options based on this feedback. Both options required that the OPOs follow the match run and the bypass code be inactivated.

> *Option 1:* The first option removed the offer timeliness requirements. Currently, mandatory sharing offers have to be made within either 3 hours or 8 hours of procurement depending on the KDPI of the kidney. By removing the time requirements, the OPOs would have more flexibility in the case of a DCD donor or expedited case.[4] However, without a time requirement, the OPO could potentially wait to make the offers until the cold time increases and limit the likelihood of offers being accepted outside of the local DSA. UNOS staff noted that it would be very difficult to determine if this was happening.
>
> *Option 2:* The second option maintained an offer timeliness requirement but changed the timeframes.

The Subcommittee initially recommended Option 2.The Committee initially agreed with the Subcommittee and discussed options for modifying the timeliness requirement. Generally, the Committee felt that these offers should be made pre-procurement and that adjusting operational parameters would permit OPOs to make more offers. After the match run is generated, the OPO can send offer notifications to centers either 3 or 5 at a time (depending on whether the kidney has been recovered or not) if they are outside the OPO's DSA. The Committee believed that the notification limits would need to be adjusted to give the OPOs more flexibility to make all mandatory sharing offers pre-procurement.

In December 2015, the Subcommittee again reviewed policy language that would require OPOs to follow the match and make all offers to very highly sensitized candidates, but the offers would have to be made

[4] Examples of expedited cases include instances in which a donor is crashing, the donor family requests an accelerated timeframe for procurement, etc.

pre-procurement. The OPOs would have been required to document the reason for not making these offers pre-procurement. The OPO representatives on the Subcommittee were very concerned that requiring documentation would greatly increase OPO member burden and still would not address concerns about expedited cases. The kidney representatives on the Subcommittee felt that the change to policy should focus on ensuring that very highly sensitized candidates are not skipped. As a compromise, the Subcommittee ultimately recommended that the OPOs would have to follow the match run, but there would not be a time requirement to prompt the OPOs to begin making offers.

The Committee agreed to this change and asked for the mandatory sharing bypass code be deactivated so that OPOs must make offers according to the match run.

Informed Consent for Multi-Organ Candidates for Kidneys Based on KDPI Greater than 85%

The Subcommittee initially recommended that the Committee clarify that the informed consent policy for kidneys based on KDPI greater than 85% applies to multi-organ candidates that are listed for both a kidney and another organ. This recommendation was consistent with how UNOS staff have interpreted the policy. Some Committee members were unaware of this policy interpretation, and the Committee was evenly divided on whether this requirement should apply to multi-organ candidates. Committee members agreed that candidates should be informed of the increased risks associated with accepting high KDPI kidneys. Some Committee members believed that policy should be consistent regardless of whether the candidate is on the kidney-alone waiting list or registered for a multi-organ transplant. However, other Committee members believed a formal consent form for a multi-organ candidate was overly burdensome because:

- Multi-organ allocation is driven by the other organ rather than the kidney
- Multi-organ candidates are unlikely to decline the offer solely due to the kidney's KDPI. Multi-organ candidates may be primarily concerned with the need for a liver, heart, lung, or pancreas and less concerned about quality or expected longevity of the kidney. Conversely, kidney-alone candidates may need to balance the urgency for a transplant versus the expected longevity of the organ.

The Subcommittee also discussed when consent for multi-organ candidates should be obtained. Consent is currently required prior to receiving offers for high KDPI kidneys.[5] Although obtaining consent early on is preferred, Subcommittee members suggested that multi-organ candidates should have up until the time of transplant to consent. One Subcommittee member voiced concerns about whether candidates experiencing fulminant liver failure would be able to properly consent at the time of transplant due to their urgent medical condition. However, other Subcommittee members did not want to deny a patient a potential lifesaving opportunity only because consent was not obtained prior to receiving offers.

The Committee generally favored extending the period for obtaining consent to up until the time of transplant. However, because of the division among the Committee members about whether written, informed consent must be obtained from multi-organ candidates, the Committee is asking for specific public comment feedback on this topic.

The proposed policy adds clarification so that the informed consent requirement, including the current timeframe for obtaining consent (i.e. prior to receiving offers), *would* apply to multi-organ candidates. The Committee is requesting specific feedback to assess whether this requirement should be changed and would like to know: (1) if the transplant community believes the informed consent requirement should apply to multi-organ candidates and (2) if so, should consent be obtained prior to receiving offers or prior

[5] Although policy requires consent before organs are offered to kidney candidates, programming currently does not require any documentation to be submitted in order to receive these offers. The proposed changes would not require any additional data collection or changes to programming if applied to multi-organ candidates.

to transplant. The Committee will consider this public comment feedback before making its ultimate recommendations to the OPTN/UNOS Board of Directors for final approval.

How well does this proposal address the problem statement?

Members of the Committee have subject matter expertise in the fields of transplant medicine and surgery, histocompatibility, and organ procurement. Because this proposal consists primarily of clarifications and clerical fixes, the Committee relied on clinical consensus rather than statistical analysis or modeling. The Committee believes that the changes outlined in this proposal clarifies kidney allocation policy and will provide more equitable access to highly sensitized candidates.

Which populations are impacted by this proposal?

This proposal has the potential to affect each of the 101,000 candidates on the kidney waiting list. The proposal may have the greatest impact on the 8,000 candidates with a CPRA 99-100%, since the policy would eliminate the current practice of bypassing these candidates after exceeding mandatory sharing requirements. Some of these very highly sensitized patients may receive transplants that otherwise they would not receive.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no expected impact to this goal.
2. *Improve equity in access to transplants:* Highly sensitized candidates may not be treated equitably across the country because some OPOs use a local bypass code to allocate kidneys after meeting the mandatory sharing requirements outlined in current policy. The proposed changes make KAS more equitable for these candidates. The updates to KAS policy may also further its original goals of improving access for difficult-to-match candidates and making better use of available kidneys.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This proposal may improve the efficiency of KAS by clarifying the roles of the OPO in instances of discrepant HLA typing and placement of national kidney offers. Additionally, this proposal corrects clerical errors.

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

Due to this proposal consisting primarily of clarifications and clerical fixes, new analyses will not be performed to evaluate its impact. However, as part of ongoing KAS monitoring efforts, the number and percentage of offers and transplants occurring in CPRA 99-100% patients (by geography: local, regional, national) will continue to be evaluated.

How will the OPTN implement this proposal?

This proposal will require a medium programming effort in UNet^{SM} to inactive the bypass code for mandatory sharing and correct the match classification titles.

Because this proposal involves both changes to policy and requires programming, it may require an instructional program.

How will members implement this proposal?

OPOs: OPOs will need to become familiar with these changes to policy. The bypass code currently used to allocate kidneys locally after meeting the minimum mandatory sharing requirements will be inactivated. OPOs will need to update their internal policies and procedures to address these policy and programming changes and educate their staff.

Transplant hospitals: Transplant hospitals will need to become familiar with changes to policy. As proposed, transplant hospitals will need to obtain written, informed consent from multi-organ candidates prior to receiving offers for kidneys with a KDPI score greater than 85%.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine reviews of OPTN members. UNOS staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements and will investigate potential policy violations.

Policy or Bylaw Language

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

5.3.C Informed Consent for Kidneys

Prior to receiving an offer for a kidney with a Kidney Donor Profile Index (KDPI) score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category. This requirement also applies to multi-organ offers that include a kidney.

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.

The transplant program must transplant all accepted, deceased donor organs into the originally designated recipient or release the deceased donor organs back to and notify the host OPO or the OPTN Contractor for further distribution. If a transplant program released an organ, it must explain to the OPTN Contractor the reason for refusing the organ for that candidate. The host OPO must then allocate the organ to other candidates according to the organ-specific policies. The host OPO may delegate this responsibility to the OPTN Contractor or to the OPO serving the candidate transplant program's DSA.

8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor and the intended recipient cannot be transplanted, the kidney ~~may be allocated according to the original HLA typing, or the receiving transplant program may reallocate the kidney locally, according to *Policy 8: Allocation of Kidneys Policy 5.9: Released Organs*.~~ must be allocated according to *Policy 5.9 Released Organs*. When reallocating the kidney, the OPO has the discretion to use either the HLA typing identified by the donor histocompatibility laboratory or the recipient HLA laboratory.

8.5.C Informed Consent for Kidneys Based on KDPI Greater than 85%

Prior to receiving an offer for a kidney with a KDPI score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category. This requirement also applies to multi-organ offers that include a kidney.

8.5.E Allocation of Kidneys by Blood Type

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-4* below:

Table 8-4: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O For offers made to candidates in ~~zero~~ 0-ABDR mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in ~~zero~~ 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.
Blood Types A, non-A_1 and AB, non-A_1B	Kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or blood type AB, non-A_1B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

8.5.G Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% can receive offers in allocation classifications 1 through 10 in allocation sequences in ~~*Table 8-6*~~ *Policy 8.5 Kidney Allocation Classifications and Rankings*, the transplant program's HLA laboratory director and the candidate's transplant physician or surgeon must review and sign a written approval of the unacceptable antigens listed for the candidate. The transplant hospital must document this approval in the candidate's medical record.

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

Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-5* below.

Table 8-5: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
2	OPO's DSA	CPRA equal to 100%, blood type identical or permissible	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	Any
4	OPO's region	CPRA equal to 100%, blood type identical or permissible	Any
5	Nation	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Any
6	Nation	CPRA equal to 100%, blood type identical or permissible	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
8	OPO's DSA	CPRA equal to 99%, blood type identical or permissible	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	Any
10	OPO's region	CPRA equal to 99%, blood type identical or permissible	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	Any
12	OPO's DSA	CPRA equal to 98%, blood type identical or permissible	Any
13	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type identical	Any
14	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	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	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
17	Nation	0-ABDR mismatch, ~~CPRA greater than or equal to 21% but no greater than 79%,~~ 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	Any
18	OPO's region	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	Any
19	Nation	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	Any
20	OPO's region	0-ABDR mismatch, top 20% EPTS ~~or 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 identical	Any
21	Nation	0-ABDR mismatch, top 20% EPTS ~~or 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 identical	Any
22	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type B	O
23	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	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	O
25	OPO's region	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	O
26	Nation	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	O
27	OPO's region	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	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
28	Nation	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	O
29	OPO's region	0-ABDR mismatch, top 20% EPTS ~~or less than 18 years old at the time of the match~~, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, and blood type permissible	Any
32	OPO's region	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, top 20% EPTS or less than 18 years old at time of match run, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	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	Any
35	Nation	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	Any
36	OPO's region	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	Any
37	Nation	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	Any
38	OPO's region	0-ABDR mismatch, top 20% EPTS ~~or 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	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
39	Nation	0-ABDR mismatch, top 20% EPTS ~~or less than 18 years old at the time of match run~~, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	OPO's DSA	Top 20% EPTS, blood type B	A2 or A2B
43	OPO's DSA	Top 20% EPTS, blood type permissible or identical	Any
44	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, blood type identical	Any
45	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Any
46	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Any
47	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
48	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
49	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type B	O
50	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	O
51	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	O
52	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
53	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
54	OPO's DSA	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	Any
55	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Any
56	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Any
57	OPO's region	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
58	Nation	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
59	OPO's DSA	EPTS greater than 20%, blood type B	A2 or A2B
60	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
61	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
62	OPO's region	Top 20% EPTS, blood type B	A2 or A2B
63	OPO's region	Top 20% EPTS, blood type permissible or identical	Any
64	OPO's region	EPTS greater than 20%, blood type B	A2 or A2B
65	OPO's region	All remaining candidates, blood type permissible or identical	Any
66	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
67	Nation	Top 20% EPTS, blood type B	Any
68	Nation	Top 20% EPTS, blood type permissible or identical	Any
69	Nation	All remaining candidates, blood type permissible or identical	Any

8.6. Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in ~~*Policies 8.5.K:*~~

~~*Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%*~~ and ~~*8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%*~~ *Policy 8.5: Kidney Allocation Classifications and Rankings* before offering both kidneys to a single candidate, unless the OPO reports to the OPTN Contractor prior to allocation that the deceased donor meets *at least two* of the following criteria:

- Age is greater than 60 years
- Estimated creatinine clearance is less than 65 mL/min based upon serum creatinine at admission
- Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery
- History of longstanding hypertension or diabetes mellitus
- Glomerulosclerosis greater than 15% and less than 50%

The kidneys will be allocated according to sequence of the deceased donor's KDPI.

~~8.7.A Mandatory Sharing~~

~~Kidneys shared as zero mismatches or for candidates with CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences in *Table 8-5* through *8-8* above must be offered within the following time limits according to *Table 8-9* below.~~

~~**Table 8-9: Organ Offer Limit**~~

~~If the donor is:~~	~~The OPO must make at least this many offers :~~	~~Then the OPO must offer the kidneys within this many hours of procurement:~~
~~KDPI ≤ 85%~~	~~10~~	~~8 hours~~
~~KDPI >85%~~	~~5~~	~~3 hours~~

8.7.~~B~~A Choice of Right versus Left Donor Kidney

If both kidneys from a deceased donor are able to be transplanted, the transplant hospital that received the offer for the candidate with higher priority on the waiting list will get to choose first which of the two kidneys it will receive.

However, when a kidney is offered to a ~~zero~~ 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8* above, or to a combined kidney and non-renal organ candidate, the host OPO determines whether to offer the left or the right kidney.

8.7.~~C~~B National Kidney Offers

~~With the exception of zero mismatched kidneys and kidneys shared nationally for 100% CPRA candidates, if a kidney is not placed in the donor hospital's DSA, then the host OPO must contact the Organ Center to assist with national placement.~~

The host OPO must allocate deceased donor kidneys according to *Table 8-10* below.

Table 8-10: National Kidney Offers

If the organ offer is for:	Then the host OPO must:
A national 0-ABDR mismatch candidate	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
A national 100% CPRA candidate in match classifications 1 through 10 in allocation sequences according to *Tables 8-5* through *8-8* above	Allocate the kidney or contact the Organ Center for assistance allocating the kidney
Any other national candidates	Contact the Organ Center for assistance allocating the kidney

~~The importing OPO must select any alternate candidates according to *Policy 8.5 Kidney Allocation Classifications and Rankings* if the kidney cannot be transplanted into the original intended candidate.~~

8.7.~~D~~C ~~Kidney-Non-renal~~ Multi-Organ~~s~~ Combinations Allocated ~~and~~ but Not Transplanted

If a multi-organ combination ~~kidney-non-renal organ~~ that includes a kidney is allocated but the kidney transplant is not performed, ~~the kidney allocated for that transplant must be immediately offered for zero antigen mismatched candidates~~ the kidney must be reallocated according to *Policy 5.9 Released Organs*.

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