

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. Revising 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. Other clarifications

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.

Kidney Allocation System (KAS) Clarifications & Clean Up

Affected Policies: Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%, Policy 8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings, Policy 8.3 Kidney Allocation Points, 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, 2014.¹ 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. Revising 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. Other clarifications

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.² 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.

¹ https://optn.transplant.hrsa.gov/media/1277/policynotice_20130701.pdf

² 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.

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. A 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 some OPOs continue to use this bypass code (see Table 5). However, very highly sensitized candidates now appear at the top of the allocation sequences instead of 0-ABDR mismatches. KAS policy also does not specify what OPOs can or must do after making the minimum number of offers if they are not accepted.

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. Very highly sensitized candidates (i.e. CPRA 99-100%) may only be compatible with 1% or less of all donors.

The Committee recommends deactivating the bypass code and removing the time restrictions (i.e. making offers within 8 or 3 hours of procurement) 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, unlike the mandatory sharing bypass code, 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 score greater than 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.

During the development of this proposal, the Committee was divided on this clarification. 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. The Committee asked (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. After reviewing public comment feedback, the Committee decide to change the timeframe to obtain consent to “any time 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.³ 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 may 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 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 *or* 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 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*).

³ This proposal only seeks to alleviate further confusion between *Policy 5.9: Released Organs* and *Policy 8: Allocation of Kidneys*. Addressing “local back-up” organ allocation is outside the scope of this proposal.

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 of policy. 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 UNetSM.⁴

5. Other Clarifications

UNOS staff also identified references to the allocation sequences throughout *Policy 8: Allocation of Kidneys* 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.

⁴ This change would be made to classifications 20, 21, 29, 38, and 39 in Table 8-5.

How was this proposal developed?

The proposal was developed through a KAS Post-Implementation Subcommittee (the Subcommittee) tasked with reviewing data trends, assessing the need for post-implementation policy clarifications, and determining the need for IT programming changes. The Subcommittee included 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

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 instead of 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 the first six months of KAS, 22 OPOs bypassed a potential transplant recipient because the minimum offers required by the mandatory sharing policy was met. **Table 2** shows the usage of the mandatory sharing bypass code during the first six months following KAS implementation.

Table 2: Usage of Bypass Code: Refusal Reason 881 – Mandatory Sharing Offer Requirements Met, 12/04/2014-05/31/2015

	Number	Description
N of candidate registrations bypassed	902	<ul style="list-style-type: none"> 53% of candidates bypassed were non-local, CPRA 99-100% 47% of candidates bypassed were other 0-ABDR mismatches
N of donors	52	<ul style="list-style-type: none"> Represents 1.3% of all recovered kidney donors For 3 donors, the code was reported more than 50 times for each donor
N of OPOs using code	22	

Note: Only match runs with final acceptance are included.

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

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.⁵ However, without a time requirement, the OPO

⁵ Examples of expedited cases include instances in which a donor is crashing, the donor family requests an accelerated timeframe for procurement, etc.

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 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 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 OPO could still use other currently available bypass codes to place the kidney in the event that the kidney becomes at risk for discard. **Table 3** shows other available bypass codes:

Table 3: Other Currently Available Bypass Codes

Code	Refusal Reason	Description
861	Operational - OPO	OPO bypassed potential recipient due to transportation logistics, including distance in relation to ischemic time or weather conditions.
862	Donor Medical Urgency	Potential recipient was bypassed due to urgent donor organ placement.
863	Offer not made due to expedited placement attempt	Potential recipient bypassed as a result of offer(s) made during an expedited placement attempt. This includes offers of expanded donor organs, OR time constraints or family time constraints.

The Committee agreed to this compromise and asked to remove the time restrictions for mandatory sharing and to deactivate the mandatory sharing bypass code so that OPOs must make offers according to the match run. The Committee did not recommend any changes based on public comment feedback (see "Was this proposal changed in response to public comment?").

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.⁶ 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 public comment proposal originally added 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. However, because of the division among the Committee members about whether written, informed consent must be obtained from multi-organ candidates, the Committee requested specific public comment feedback on this topic. The Committee asked (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.

Based on public comment, the Committee decided to extend the timeframe for obtain consent to “any time prior to transplant” (see “Was this proposal changed in response to public comment?”).

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 mainly relied on clinical consensus rather than statistical analysis or modeling. The Committee believes that the changes outlined in this proposal clarify kidney allocation policy and will provide more equitable access to highly sensitized candidates.

Was this proposal changed in response to public comment?

This proposal received comments primarily on the proposed changes to mandatory sharing and the informed consent requirement for multi-organ candidates for kidneys based on KDPI greater than 85%. As a result, the Committee did not recommend any post-public comment changes to the proposed policy on maintaining consistency through kidney allocation policy with regard to *Policy 5.9: Released Organs*, correcting match classification language, or clerical changes. Ultimately, the Committee only made one

⁶ 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.

post-public comment to change the timeframe for obtaining consent up until the time of transplant. The Committee’s considerations on mandatory sharing and the informed consent requirement are outlined below.

Mandatory Sharing

The majority of the regions (7 of 11) supported the proposed changes. Several committees, including the OPO Committee, also expressed support for these changes.

Comment Theme: Increase in Cold Ischemia Time (CIT) and Discard Rate

Multiple groups (including those that supported the proposed changes) expressed concern that a prolonged allocation time will increase CIT and the discard rate.

Response: Despite concerns expressed during public comment, subcommittee members reiterated that although there may be many candidates on the match run in these classifications, this may be the only (“once in a lifetime”) offer for a very highly sensitized candidate in these classifications. An OPO could still use other currently available bypass codes to place the kidney in the event that the kidney becomes at risk for discard.

In addition to discussing this comment theme, the Subcommittee and Committee also reviewed additional data post-public comment. As shown by the bolded numbers in **Table 4**, during the 12 months post-KAS implementation:

- about 6-7% of match runs included more than 10 registrations for a kidney with a KDPI 0-85%
- about 3%-5% of match runs included more than 5 registrations for a kidney with a KDPI greater than 85%

Table 4: Kidney Match Runs by Number of Mandatory Share Registrations

# mandatory share (non-local CPRA 99-100 or OMM) registrations on match run	KDPI ≤85% 1st 6 months N (%)	KDPI ≤85% 2nd 6 months N (%)	KDPI >85% 1st 6 months N (%)	KDPI >85% 2nd 6 months N (%)
0	1,458 (42.2)	1,619 (45.0)	342 (61.1)	386 (65.1)
1	700 (20.3)	710 (19.7)	99 (17.7)	103 (17.4)
2-5	825 (23.9)	829 (23.0)	89 (15.9)	87 (14.7)
6-10	239 (6.9)	227 (6.3)	18 (3.2)	11 (1.9)
>10	233 (6.7)	212 (5.9)	12 (2.1)	6 (1.0)
All	3,455 (100)	3,597 (100)	560 (100)	593 (100)

For “easy-to-match” donors, there may be dozens or even hundreds of candidates in the mandatory share classifications on a match run. However, histocompatibility testing requirements, implemented on January 21, 2016, take into account HLA-DQA1 and HLA-DPB1 as unacceptable antigens to automatically avoid those donors if these unacceptable antigens are listed. These measures may further refine the number of candidates that appear in the mandatory share classifications.

Previously, the Subcommittee had reviewed the bypass code usage during the first six months following the implementation of KAS. The Subcommittee compared the bypass code utilization to the second six months of KAS. Although there were fewer candidate registrations bypassed, **Table 5** shows that some OPOs, but not all of the 58 OPOs are using this bypass code. This further supports the Committee's belief that very highly sensitized candidates may not be treated equitably across the country.

Table 5: Usage of Bypass Code Refusal Reason 881 – Mandatory Sharing Offer Requirements Met

	1 st 6 months Post-KAS (12/4/2014 – 6/3/2015)	2 nd 6 months Post-KAS (6/4/2015 – 12/3/2015)
N of candidate registrations bypassed	902	537
% bypassed with CPRA 99-100	52%	61%
% bypassed other 0-ABDR mismatch	48%	39%
N of donors	52	49
N of OPOs using bypass code	22	28
Total number of donors with match runs	3,404	3,583
% of donor match runs with bypass code used	1.5%	1.4%

Note: Only match runs with final acceptance are included.

Due to the overall level of support for the proposed changes, the Subcommittee did not recommend any changes to the proposal. The Committee agreed with the Subcommittee's recommendation and did not make any changes to this portion of the policy proposal (18 yes, 0 no, 1 abstention). The Committee maintains that KAS was intended to make the system more equitable for highly sensitized patients and not just those patients that are in the first 10 or first 5 on the match run. Committee members also noted that concerns about discard rate and CIT may be better addressed through other projects such as the system optimization project sponsored by the OPO Committee which will look at the organ offer process as a whole. The IT Customer Council (created by UNOS IT comprised of Transplant Coordinators, Surgeons, Lab Directors, etc.) is also considering leading a project to collaborate with the committees and UNOS staff to identify and create more definitive bypass and refusal codes to identify issues that may affect organ placement.

Comment Theme: Changes Will Need to Be Monitored

The OPO Committee and ASTS noted that the impact of the proposed changes should be monitored and evaluated.

Response: The proposal's evaluation plan does not outline additional evaluation outside of the ongoing monitoring for KAS. UNOS already tracks discard rates by KDPI on a monthly basis. If approved by the OPTN/UNOS Board of Directors, the Kidney Committee could request a deeper analysis if there was an increase in discards or CIT post-implementation.

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

OPTN Committees: In general, most of the OPTN committees that commented on the proposal favored obtaining consent as proposed in the public comment document. The Thoracic, Liver, and Patient Affairs Committees supported obtaining informed consent prior to transplant. The Pancreas Transplantation Committee did not believe there should be a requirement due to the rarity of using a high KDPI kidney for a simultaneous pancreas-kidney transplant. The Pancreas Committee also expressed concern that the requirement would put policy in place of medical judgement.

Regions: The regions were split on this clarification with six regions either in favor of the proposed clarification as written or changing the timeframe to prior to transplant. Five of the regions did not believe this informed consent requirement should apply to multi-organ candidates.

Comment Theme: Maintaining Consistency with Kidney-Along Policy and Consent for Other High-Risk Designations

The Membership and Professional Standards Committee (MPSC) and the American Society for Transplant Surgeons (ASTS) supported obtaining consent as proposed to maintain consistency with both kidney-alone policy and other issues that patients need to be informed on (such as potential infections or other high-risk designations).

Comment Theme: Lack of Data on Risks/Outcome for Multi-Organ Candidates

The main theme among the regions was that without the data on risks/outcomes for multi-organ candidates, transplant programs cannot inform on the risks. However, the American Society for Transplantation (AST) also noted that without data we do not know that KDPI does *not* impact outcomes.

Response: Subcommittee members noted that it would be difficult to determine the impact of the KDPI score on a SLK recipient that accounts for all factors. However, a subsequent, post-public comment literature review identified two papers that demonstrated poorer renal outcomes in simultaneous liver-kidney recipients with extended criteria donor (ECD) kidneys.⁷

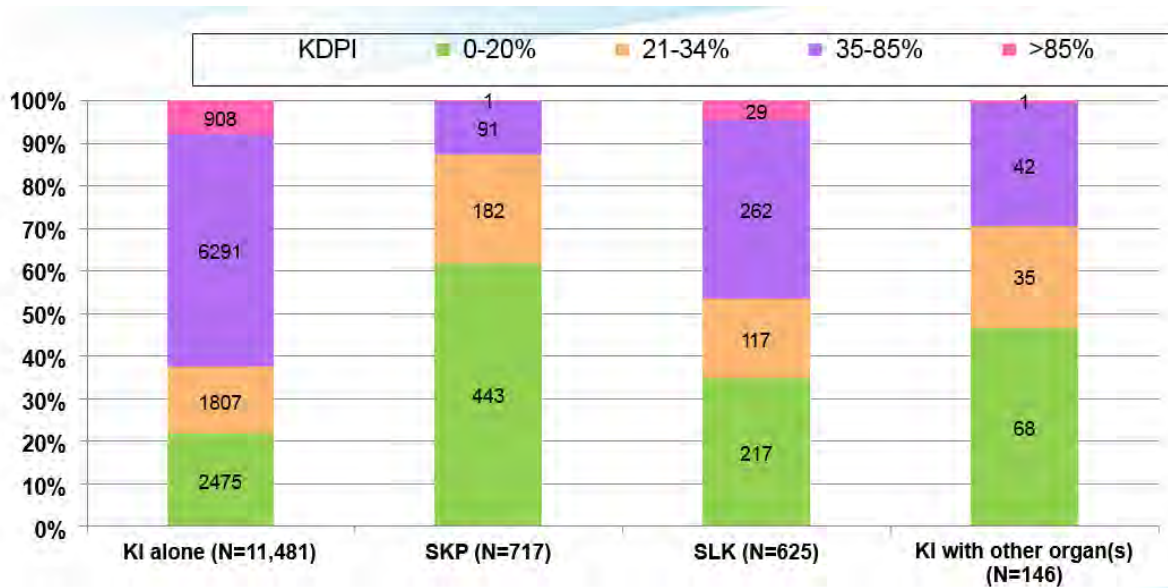
The Subcommittee reviewed the KDPI distribution among deceased donor kidney transplants in 2015, as shown in **Table 6**. This data showed multi-organ candidates receive kidneys with a high KDPI, but they are rare. In 2015, 31 of approximately 1,500 multi-organ transplants used a kidney with a KDPI greater than 85%.

⁷ ECD was a previous kidney donor quality metric that was replaced with the KDPI when the new KAS was implemented on December 4, 2014. A kidney with a high KDPI is similar to an ECD kidney.

Levitsky J, Baker T, Ahya SN, Levin ML, Friedewald J, Gallon L, Ho B, Skaro A, Krupp J, Wang E, Spies SM. Outcomes and native renal recovery following simultaneous liver–kidney transplantation. *American Journal of Transplantation*. 2012 Nov 1;12(11):2949-57.

Van Wagner LB, Baker T, Ahya SN, Norvell JP, Wang E, Levitsky J. Outcomes of patients with hepatitis C undergoing simultaneous liver–kidney transplantation. *Journal of hepatology*. 2009 Nov 30;51(5):874-80.

Table 6: KDPI Distribution Among Deceased Donor Kidney Transplants in 2015



Because the majority of the responses supported obtaining informed consent, the Subcommittee decided to keep the requirement, but ultimately recommended changing the timeframe for obtaining the consent up until the time of transplant. This decision was largely driven by the idea that a multi-organ candidate's circumstances may change from the time of registration to the time of transplant. A multi-organ candidate that may not initially consent prior to receiving organ offers for a kidney with a KDPI greater than 85%. However, as the need for a transplant becomes more urgent, the candidate may be willing to accept these kidneys. This change will allow the greatest degree of flexibility for obtaining consent, but it would not prevent transplant programs from creating more stringent standards for their particular program if they chose (i.e. to obtain consent at the time of listing or prior to receiving offers).

The Committee reviewed this recommendation and reiterated many of the same concerns expressed during the development of this proposal. Namely that the other organ drives the offer. Several committee members also agreed with the concerns over the limited data to explain adequately the risks to a multi-organ candidate. Conversely, other committee members agreed that there should be consistency with kidney-alone policy. Individual committee members also expressed the following:

- While candidates must consent for a higher risk kidney, they do not have to consent for a higher risk liver.
- Because the other organ drives the offer, the consent may not be explained by a member of the renal community who is familiar with the risks of accepting a high KDPI kidney.
- Committee members were concerned that this was pro forma formality rather than a true understanding of the scope of the risks.

Ultimately, committee members agreed that the majority of the public comment responses supported obtaining informed consent. While some might find it ideal to obtain consent prior to receiving offers, allowing up until the time of transplant gives programs the most flexibility and is patient-centric. The Committee approved the post-public comment change (17 yes, 0 no, 2 abstentions).

Which populations are impacted by this proposal?

This proposal has the potential to affect each of the approximately 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 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 clarifies the labels in the classification tables and other inconsistencies.

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. If approved by the OPTN/UNOS Board of Directors, the Kidney Committee could request a deeper analysis if there was an increase in discards or CIT post-implementation.

How will the OPTN implement this proposal?

This proposal will require a large programming effort in UNetSM to deactivate 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 transplant for kidneys with a KDPI score greater than 85%. These changes will not prohibit a transplant program from obtaining consent earlier (i.e. at the time of listing or prior to receiving offers).

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?

Members will be expected to comply with requirements in the proposed language. In addition to the routine monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

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.

Additionally, the following change to routine site surveys will occur:

Policy 5.3.C: Informed Consent for Kidneys Based on KDPI Greater than 85%

At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Kidney-alone transplant recipients who received a kidney with a KDPI score greater than 85% gave written informed consent to receive offers for kidneys with a KDPI score greater than 85%
- Multi-organ transplant recipients whose transplant included a kidney with a KDPI score greater than 85% gave written informed consent to receive the kidney before it was transplanted

(Note: Upon implementation, monitoring of Policy 5.3.C *Informed Consent for Kidneys Based on KDPI Greater than 85%* will replace monitoring of current Policy 8.5.C *Informed Consent for Kidneys Based on KDPI Greater than 85%*)

Policy or Bylaw Language

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

1 **RESOLVED**, that changes to Policies 5.3.C (Informed Consent for Kidneys Based on KDPI Greater
 2 than 85%), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA)
 3 Typings), 8.3 (Kidney Allocation Points), 8.5.C (Informed Consent for Kidneys Based on KDPI
 4 Greater than 85%), 8.5.D (Sorting Within Each Classification), 8.5.E (Allocation of Kidneys by
 5 Blood Type), 8.5.F (Prior Living Organ Donors), 8.5.G (Highly Sensitized Candidates), 8.6 (Double
 6 Kidney Allocation), 8.7.B (Choice of Right versus Left Donor Kidney), 8.7.C (National Kidney
 7 Offers), and 8.7.D (Kidney-Non-renal Organs Allocated and Not Transplanted), as set forth below,
 8 are hereby approved, effective September 1, 2016.

9 **FURTHER RESOLVED**, that changes to Policies 8.5.H (Allocation of Kidneys from Deceased
 10 Donors with KDPI Scores less than or equal to 20%) and 8.7.A (Mandatory Sharing), as set forth
 11 below, are hereby approved, effective pending implementation and notice to OPTN members.

12 **5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%**

13 Prior to receiving an offer for a kidney with a Kidney Donor Profile Index (KDPI) score greater
 14 than 85%, transplant programs must obtain written, informed consent from each kidney candidate
 15 willing to receive offers for kidneys in this category. This requirement also applies to multi-organ
 16 offers that include a kidney; however, this informed consent may be obtained any time prior to
 17 transplant.

18 **8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte** 19 **Antigen (HLA) Typings**

20 Allocation of deceased donor kidneys is based on the HLA typing identified by the donor
 21 histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the
 22 deceased donor and the intended recipient cannot be transplanted, the kidney may be allocated
 23 according to the original HLA typing, or the receiving transplant program may reallocate the
 24 kidney locally, according to ~~Policy 8: Allocation of Kidneys~~ ~~Policy 5.9: Released Organs~~. the
 25 kidney must be allocated according to ~~Policy 5.9: Released Organs~~. When reallocating the
 26 kidney, the OPO has the discretion to use either the HLA typing identified by the donor
 27 histocompatibility laboratory or the recipient HLA laboratory.
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30 **8.3 Kidney Allocation Points**

31 Candidates receive points according to *Tables 8-1* and *8-2* below.

32 **Table 8-1: Kidney Points**

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points
Registered for transplant and meets the qualifying criteria described in <i>Policy 8.4: Waiting Time</i>	8.5.H <u>G</u> , 8.5.H <u>I</u> , 8.5.H <u>J</u> , or 8.5.K <u>J</u>	1/365 points for each day since the qualifying criteria in <i>Policy 8.4: Waiting Time</i>
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H <u>G</u> , 8.5.H <u>I</u> , or 8.5.H <u>J</u>	4 points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.HG, 8.5.HI, or 8.5.II	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.HG, 8.5.HI	1 point
A prior living donor	8.5.HG, 8.5.HI, or 8.5.II	4 points
Sensitized (CPRA at least 20%)	8.5.HG, 8.5.HI, or 8.5.II	See Table 8-2: Points for CPRA
A single HLA-DR mismatch with the donor*	8.5.HG, 8.5.HI, or 8.5.II	1 point
A zero HLA-DR mismatch with the donor*	8.5.HG, 8.5.HI, or 8.5.II	2 points

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*Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed “homozygous” at that locus.

Table 8-2: Points for CPRA

If the candidate’s CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

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40 **8.5 Kidney Allocation Classifications and Rankings**

41 ~~**8.5.C Informed Consent for Kidneys Based on KDPI Greater than 85%**~~

42 ~~Prior to receiving an offer for a kidney with a KDPI score greater than 85%, transplant programs~~
43 ~~must obtain written, informed consent from each kidney candidate willing to receive offers for~~
44 ~~kidneys in this category.~~

45
46 **8.5.DC Sorting Within Each Classification**

47 Within each classification, candidates are sorted in the following order:

- 48
49 1. Total points (highest to lowest)
50 2. Date and time of the candidate's registration (oldest to most recent)

51
52 ~~**8.5.ED Allocation of Kidneys by Blood Type**~~

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

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56 **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 <u>0-</u> <u>ABDR</u> 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 <u>0-</u> <u>ABDR</u> mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Types A, non-A₁ and AB, non-A₁B	Kidneys may be transplanted into candidates with blood type B who meet <i>all</i> of the following criteria: <ol style="list-style-type: none"> 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A₁ or blood type AB, non-A₁B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting blood type A, non-A₁ and blood type AB, non-A₁B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

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8.5.FD Prior Living Organ Donors

A kidney candidate will be classified as a prior living donor if *all* of the following conditions are met:

1. The candidate donated for transplantation, within the United States or its territories, at least *one* of the following:
 - Kidney
 - Liver segment
 - Lung segment
 - Partial pancreas
 - Small bowel segment.
2. The candidate's physician reports *all* of the following information to the OPTN Contractor:
 - a. The name of the recipient or intended recipient of the donated organ or organ segment
 - b. The recipient's or intended recipient's transplant hospital
 - c. The date the donated organ was procured

8.5.GF 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~~ according to *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.HG 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, <u>CPRA greater than or equal to 21% but no greater than 79%</u> , 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	A2 or A2B
68	Nation	Top 20% EPTS, blood type permissible or identical	Any
69	Nation	All remaining candidates, blood type permissible or identical	Any

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[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

94 **8.6. Double Kidney Allocation**

95 An OPO must offer kidneys individually through one of the allocation sequences in *Policies 8.5.K:*
 96 *Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85% and 8.5.H: Allocation of*
 97 *Kidneys from Deceased Donors with KDPI Scores less than or equal to 20% Policy 8.5: Kidney Allocation*
 98 *Classifications and Rankings* before offering both kidneys to a single candidate, unless the OPO reports
 99 to the OPTN Contractor prior to allocation that the deceased donor meets *at least two* of the following
 100 criteria:

- 101
- 102 • Age is greater than 60 years
- 103 • Estimated creatinine clearance is less than 65 mL/min based upon serum creatinine at admission
- 104 • Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery
- 105 • History of longstanding hypertension or diabetes mellitus
- 106 • Glomerulosclerosis greater than 15% and less than 50%

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 108 The kidneys will be allocated according to sequence of the deceased donor’s KDPI.
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110 **8.7 Administrative Rules**

111 **8.7.A — Mandatory Sharing**

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

115 **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

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 117 **8.7.BA Choice of Right versus Left Donor Kidney**

118 If both kidneys from a deceased donor are able to be transplanted, the transplant hospital that
 119 received the offer for the candidate with higher priority on the waiting list will get to choose first
 120 which of the two kidneys it will receive.
 121

122 However, when a kidney is offered to a ~~zero~~ 0-ABDR mismatched candidate, a candidate with a
 123 CPRA greater than or equal to 99% in classifications 1 through 10 in allocation sequences
 124 according to *Tables 8-5 through 8-8* above, or to a combined kidney and non-renal organ
 125 candidate, the host OPO determines whether to offer the left or the right kidney.
 126

127 **8.7.CB National Kidney Offers**

128 ~~With the exception of zero mismatched kidneys and kidneys shared nationally for 100% CPRA~~
 129 ~~candidates, if a kidney is not placed in the donor hospital's DSA, then the host OPO must contact~~
 130 ~~the Organ Center to assist with national placement.~~
 131 The host OPO must allocate deceased donor kidneys according to Table 8-9 below.

132 **Table 8-9: National Kidney Offers**

If the organ offer is for:	Then the host OPO must:
<u>A national 0-ABDR mismatch candidate</u>	<u>Allocate the kidney or contact the Organ Center for assistance allocating the kidney</u>

If the organ offer is for:	Then the host OPO must:
A national 100% CPRA candidate in match classifications 1 through 10 in allocation sequences according to <i>Tables 8-5 through 8-8</i>	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

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~~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.DC Kidney-Non-renal Multi-Organ 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*.

#