

At-a-Glance

- **Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates** (Modifications to Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys))
- **Sponsoring Committee:** Kidney Transplantation Committee
- The intent of this modification is to reduce the number of mandatory shares of zero antigen mismatched kidneys for unsensitized kidney transplant candidates, resulting in fewer payback debts, shorter cold ischemic times for kidneys, and improved efficiency of the OPTN kidney allocation system.
- **Affected groups**
Kidney Transplant Candidates, Kidney/Pancreas Transplant Candidates, OPO Data Coordinators, OPO Medical Directors, Transplant Coordinators, Transplant Data Coordinators, Transplant Physicians, Transplant Program Directors, Transplant Social Workers, Transplant Surgeons, Histocompatibility Laboratories

Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates (Modifications to Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys))

Sponsoring Committee: Kidney Transplantation Committee

Summary and Goals of the Proposal:

With few exceptions, current policy requires mandatory sharing of kidneys that are a zero antigen mismatch, regardless of other donor or candidate characteristics. The receiving organ procurement organization (OPO) then incurs an obligation to pay back a kidney. This modification would eliminate mandatory sharing at the regional and national levels for adult candidates who have a sensitization level (PRA or CPRA) less than 20%. The intent of this modification is to reduce the number of mandatory shares for unsensitized adult candidates, resulting in fewer payback debts, shorter cold ischemic times for kidneys, and improved efficiency of the OPTN kidney allocation system.

Background and Significance of the Proposal:

In response to several OPTN member concerns regarding the zero-antigen mismatch sharing policies and related kidney payback policies, the Kidney Transplantation Committee conducted a review of the effect of these policies on transplant candidates, transplant centers, and the OPTN. Based on this review, the Committee determined that while the graft survival benefit of a zero mismatched kidney is still significant, the benefit may no longer be sufficient to support national mandatory sharing for all candidates. Additionally, unintended consequences of these policies include the limited ability for some OPOs to perform simultaneous pancreas-kidney (SPK) transplants and unacceptable inefficiencies in the kidney allocation system. The following is a summary of the policy history and performance data reviewed by the Committee.

History of Zero-Antigen Mismatch/Payback Policies

The original policy for mandatory sharing of 0-ABDR kidneys was based on the superior graft survival outcomes observed in the recipients. Improvements in immunosuppression and other advances in organ transplantation have narrowed the gap between graft survival of recipients of perfectly matched kidneys (i.e., zero antigen mismatched kidneys) and recipients of less well-matched kidneys. In 1995, the OPTN Board of Directors eliminated the points priority for matching at the HLA-A locus and in 2003, eliminated the points priority for matching at the HLA-B locus. Currently, allocation priority for HLA matching only exists for candidates with zero-antigen mismatch offers, and points are awarded only for candidates with zero or one mismatch at the HLA-DR locus.

The payback policies were instituted as a mechanism for addressing the imbalances created by the zero antigen mismatch sharing policies. Since zero-antigen mismatches are more frequent among those with common antigens (who are often more likely to be white candidates), the payback policy is intended to rebalance the allocation system so that no patient population benefits from the zero antigen mismatch sharing rules to the disproportionate harm of any other patient population. Therefore, as long as the

rules for sharing zero antigen mismatched kidneys are in place, a mechanism for restoring system balance is necessary.¹

Current policy states that when an OPO accepts a zero-antigen mismatch offer from another OPO, it is required to “pay back” the kidney with a kidney from the same blood group after at least two debts have been accrued. Kidneys are offered as paybacks after being offered to highly sensitized zero-antigen mismatch candidates, prior living organ donors, and children (if the kidney is from a donor younger than 35 years old). Some OPOs have reported difficulty in placing payback kidneys for several reasons. One cited reason is that OPOs are not required to accept payback kidneys. Therefore, the OPO may choose to turn down offers from what it views to be marginal donors and may wait for a more ideal kidney to be offered. Since the pediatric priority policy for donors under the age of 35 went into effect in 2005, some OPOs have observed a decrease in the percent of kidneys from donors <35 available for payback offers. The Kidney Committee has also reviewed acceptance rates for kidneys offered as paybacks and has found that few of the kidneys offered for paybacks are actually accepted and acceptance rates vary widely based on OPO.

The penalties for exceeding the stated payback debt levels have not served as an effective governor for the zero-antigen mismatch and payback policies (Figure 2). One penalty reprioritizes unsensitized candidates from OPOs with payback debt levels greater than 10 to the bottom of the match run category for zero-antigen mismatches. Another penalty states that when an OPO reaches a debt level of 9 kidneys across all blood groups, it may no longer retain a kidney for local simultaneous kidney-pancreas (SPK) transplantation. The kidney must be offered as a payback. The result has been a decrease in SPK transplantation in some of OPOs with consistently moderate to high debt levels. In 2006 and 2007, the Pancreas Transplantation Committee reviewed complaints from several pancreas transplant programs that were unable to perform SPK transplants due to kidney payback debt levels. In at least one instance, this inactivity led to an inquiry by the Membership and Professional Standards Committee (MPSC). The Kidney Transplantation Committee, along with the Pancreas Transplantation Committee believe that this situation is disproportionately affecting candidates listed for kidney-pancreas transplantation.

In February 2006, the Pancreas Transplantation Committee offered the following recommendation to the Kidney Committee:

****Resolved**, that the Pancreas Transplantation Committee recommends to the Kidney Transplantation Committee elimination from the national system for kidney allocation (i) requirements for sharing kidneys for zero antigen mismatch between donor and candidate except at the local level of organ distribution and in the case of highly sensitized candidates (as the term highly sensitized is being defined by the Kidney Committee), as well as (ii) kidney payback requirements. (The Pancreas Committee noted that it is not opposed to continuing zero antigen mismatch allocation requirements for pediatric candidates; this seemed less relevant for comment by the Committee.)

Vote: 12 For; 0 Against; 1 Abstention

¹ Report of the OPTN/UNOS Kidney and Pancreas Transplantation Committee to the Board of Directors. Washington, DC. November 2000.

At the time that this resolution was passed, the Kidney Transplantation Committee believed that development of a new kidney allocation system was nearing completion. The Committee planned to address these concerns in the new system and decided that the current system should not be altered since it was expected to be phased out over the coming year. As an interim approach, the Committee advised OPOs that were consistently violating the maximum payback debt level to limit acceptance of zero-antigen mismatch offers to sensitized candidates and pediatric candidates as a way of reducing the number of payback debts incurred. Some transplant centers expressed that this was an unacceptable approach because it would require surgeons to refuse acceptable organs for their patients. Additionally, centers with kidney and pancreas transplant programs reported that centers without pancreas transplant programs were not willing to refuse zero-antigen mismatch offers so that SPK transplants could occur. Ultimately, OPO members of the Kidney Transplantation and Pancreas Transplantation Committees reported that these problems could not be solved at the local level and that changes to the national policy were necessary.

The Kidney Transplantation Committee has continued to monitor payback debt levels for all OPOs. Unfortunately, payback debt levels have continued to rise, substantially in some OPOs, and the efforts to counsel OPOs with excessive debt levels have not been successful. The Committee requested data analyses to determine if a policy modification is necessary to bring the system back into balance.

Supporting Evidence

The Committee reviewed an analysis of the number of transplants by zero antigen mismatch, other mismatch, and payback kidneys. In 2006, nearly 14% of all deceased donor kidney transplants were zero antigen mismatches (n = 2,156). From this analysis, it became apparent that minority candidates received far fewer zero antigen mismatch transplants than white candidates (Figure 1). While this finding was expected, the distribution of payback kidneys by ethnicity did not rebalance the allocation system. Minority candidates were also less likely than white candidates to receive a transplant with a payback kidney.

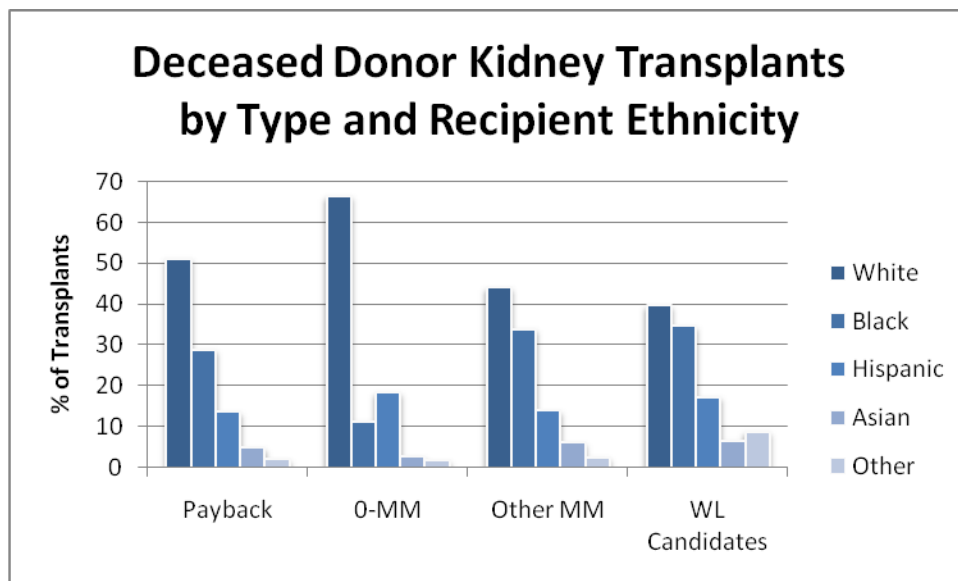
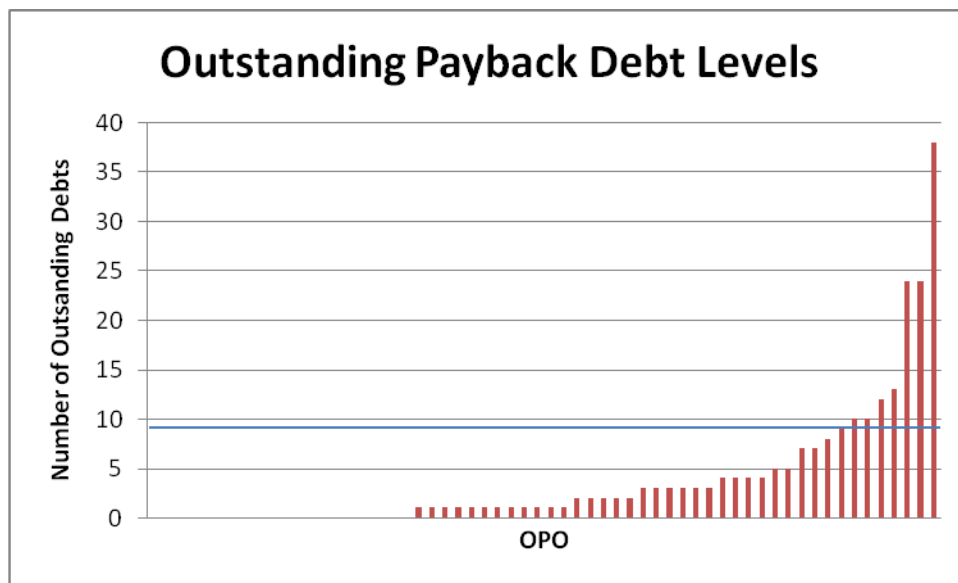


Figure 1: Deceased Donor Kidney Transplants in 2006 by Type and Ethnicity

The Committee also observed inefficiencies related to the kidney payback system that are prohibiting some OPOs from reducing their debt levels. In 2006, only 6.9% of all of the kidneys offered as payback were accepted. Furthermore, acceptance rates for OPOs that were owed more than 10 kidney paybacks ranged from 8.3% to 36.4% suggesting that some OPOs are much more likely to accept kidney payback offers than others. While the majority of OPOs have debt levels lower than the maximum of 9 (Figure 2), the limited acceptance of payback offers has a direct effect on waitlisted kidney and kidney-pancreas candidates at OPOs with debt levels ≥ 10 . When OPOs are not able to maintain acceptable debt levels (either through refusal of zero-antigen mismatched offers, or through repayment of payback debts), their unsensitized waitlisted candidates are reprioritized to the bottom of the zero-antigen mismatched sequence (OPTN/UNOS Policy 3.5.3.3.1.xi and 3.5.3.3.2.xii)



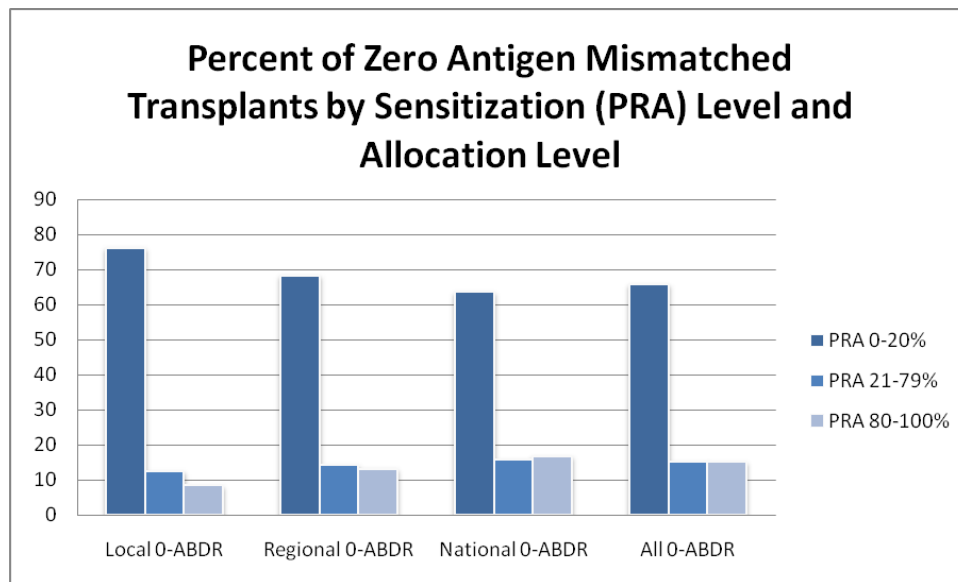


Figure 3: Percent of Zero Antigen Mismatched Transplants by Sensitization (PRA) Level and Allocation Level

Expected Impact on Program Goals, Strategic Plan and Adherence to OPTN Final Rule

This proposal is expected to improve the operating efficiency of the OPTN. While the efficiency gains are expected to improve the distribution of organs, the Committee does not expect to be able to observe any measurable gains in number of transplants or organs recovered per donor.

Plan for Evaluation of the Proposal

The Kidney Committee will review data at six month intervals to ensure that this change in allocation serves its intended purpose.

What questions/hypotheses are guiding the evaluation of the proposal?

Answers to these questions should help determine whether or not the proposal is meeting its intended goal(s).

- Has the number of non-local payback debts decreased since policy change?
- Has the number of OPOs with more than 9 debts decreased since policy change?
- Have the OPO's with more than 9 debts been able to decrease their debt levels since policy change?
- Have the number and percent of 0-mismatched transplants changed since policy implementation?
- Has overall post-transplant survival changed since policy implementation?

Policy Performance Measures:

The following data will be provided:

- Number of payback debts by OPO and blood group before and after policy change
- Number of OPOs with more than 9 debts before and after policy change
- For OPO's with more than 9 debts before policy change, number of debts before and after policy change

- Number and percent of zero and non-zero mismatched transplants by age group, location, and sensitization level before and after policy change
- Graft and patient survival for adults and pediatrics before and after policy change (Note: this will be provided when there is sufficient post-transplant follow-up information, i.e., after the policy is in place for about 24 months)

Plan for Monitoring Member Compliance

If approved, this change will be programmed into UNetsm so that the kidney match does not display zero mismatch candidates with a PRA < 20% as mandatory shares. OPOs are expected to allocate kidneys according to the match run sequence. UNOS reviews all organ allocations and forwards instances of potential non-compliance (i.e. allocations that do not follow the match run sequence) to the OPTN/UNOS Membership and Professional Standards Committee for its review.

Additional Data Collection

This proposal will not result in any additional data collection.

Policy Proposal

Based on this information, the Committee voted in August 2007 to revisit this issue with the following resolution:

****Resolved**, that the Kidney Transplantation Committee will send out for public comment proposed modifications to the current zero-antigen mismatch policy and related kidney payback policies to limit mandatory sharing of zero-antigen mismatch at the regional and national levels to pediatric candidates and candidates with a PRA level $\geq 20\%$. Kidneys shared as zero-antigen mismatches will still result in a payback obligation which must be fulfilled by the OPO that receives the zero-antigen mismatch.

****Further resolved** that, OPOs currently in violation of the maximum payback debt level of nine must submit to the Kidney Transplantation Committee, a written corrective action plan that describes how the OPO intends to repay its current debts.

18 in favor, 1 against, 0 abstentions

The modifications to policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) appear below. For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

3.5.3 Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is ~~a candidate~~ a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14, DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into UNetSM prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.

3.5.3.3 Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors¹ if there is any candidate a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations

for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors¹, if there is ~~any candidate~~ a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ

donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.3.3.1 First to identical blood type zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:

- i local candidates; then to
- ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- iii 80% or higher PRA candidates on the regional waiting list; then to
- iv 80% or higher PRA candidates on the national waiting list; then to
- v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
- vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
- viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- ix 21%-79% PRA candidates on the regional waiting list; then to
- x 21%-79% PRA candidates on the national waiting list; then to
- xi ~~less than or equal to 20% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for candidates on the list of OPOs that owe ten or more short term payback obligations~~

~~and/or do not meet applicable thresholds for reducing long term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of “short term” and “long term” debt); then to~~

~~xii less than or equal to 20% PRA candidates on the regional waiting list, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt); then to~~

~~xiii less than or equal to 20% PRA candidates on the national waiting list, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt); then to~~

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched candidates, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and, then, to blood type A and AB zero antigen mismatched candidates, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and (2) in the case of blood type A, B, and AB donor kidneys, to ~~all~~ all pediatric and sensitized adult candidates (CPRA > 20%) who are compatible blood type-blood type compatible zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below:

i local candidates; then to

ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

- iii 80% or higher PRA candidates on the regional waiting list; then to
- iv 80% or higher PRA candidates on the national waiting list; then to
- v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
- vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
- viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- ix 21%-79% PRA candidates on the regional waiting list; then to
- x 21%-79% PRA candidates on the national waiting list; then to
- ~~xi less than or equal to 20% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for candidates on the list of OPOs that owe ten or more short term payback obligations and/or do not meet applicable thresholds for reducing long term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short term" and "long term" debt); then to~~
- ~~xii less than or equal to 20% PRA candidates on the regional waiting list, except for candidates on the list of OPOs that owe ten or more short term payback obligations and/or do not meet applicable thresholds for reducing long term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long term" debt); then to~~
- ~~xiii less than or equal to 20% PRA candidates on the national waiting list, except for candidates on the list of~~

~~OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt); then to~~

~~xiv less than or equal to 20% PRA candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt), ranked by OPO in inverse order of the highest number of payback obligations owed by the OPO if more than one OPO is in this category.~~