

**UNITED NETWORK FOR ORGAN SHARING  
POLICY PROPOSALS**

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**Background**

The United Network for Organ Sharing (UNOS) is a tax-exempt medical, scientific, and educational organization. On October 1, 2000, UNOS received a federal contract to continue operation of the national Organ Procurement and Transplantation Network (OPTN) and development of an equitable, scientific and medically-sound organ allocation system. The OPTN is charged with developing by-laws and policies that maximize utilization of organs donated for transplantation, assuring the quality of care for transplant patients, and addressing other complex medical issues related to organ transplantation in the United States. All by-laws and policies receive broad input from numerous constituencies including transplant patients, patient and donor families, the OPTN membership, and concerned individuals and organizations throughout the United States.

By-Laws and policies are adopted by the UNOS/OPTN Board of Directors pursuant to the UNOS contract with the United States Department of Health and Human Services (DHHS) and after circulation and discussion among organ transplant professionals and patient representatives. These by-laws and policies have been submitted to the Secretary of DHHS for review and are considered voluntary guidance to OPTN members until approved as OPTN rules and requirements by the Secretary of DHHS. UNOS is responsible for updating these by-laws and policies and for monitoring compliance by OPTN members. Instances of noncompliance with by-laws and policies may lead to disciplinary action and designation as a member-not-in-good-standing by the Board of Directors. In addition, instances of non-compliance are reported to the Secretary of DHHS.

The proposals which follow address issues brought before the UNOS/OPTN Board of Directors on November 16-17, 2000 and the UNOS/OPTN Executive Committee on January 16, 2001 by the Liver and Intestinal Organ Committee. This document also offers for public comment, proposals which address issues considered during the September 2000 meeting of the Minority Affairs Committee, and the January 2001 meetings of the Kidney and

Pancreas Transplantation Committee and Liver and Intestinal Organ Transplantation Committee. Following public comment and reconsideration by the appropriate committee(s), all proposals in this document may be offered for consideration by the UNOS/OPTN Board of Directors at its June 28-29, 2001 meeting in San Diego, California.

### **Circulation of Notice**

UNOS maintains a public comment distribution list for policy and by-law proposals. To be included on the distribution list, submit a written request to UNOS at the address below. All policy and by-law proposals issued for public comment are mailed to the distribution list. UNOS accepts comments from the public for at least 45 days after publication of the proposals and public hearings on the proposals are arranged if warranted.

### **Comment Deadline**

The proposals in this document are being issued for public comment on **March 16, 2001**. To be considered, comments must be submitted in writing, or by completing the enclosed Public Comment Response Form, and sent to the UNOS contact person at the following address by **May 2, 2001**:

**United Network for Organ Sharing  
P.O. Box 13770  
1100 Boulders Parkway, Suite 500  
Richmond, VA 23225  
FAX (804) 330-8596**

*These policy proposals also are available on the Internet at [www.unos.org](http://www.unos.org). Comments on these proposals may be submitted electronically at this site.*

### **UNOS Contact Persons**

Inquiries regarding the policy proposals in this document should be made to the appropriate UNOS Regional Administrator at (804) 330-8500. The UNOS Regional Administrators are as follows:

#### **Fred Geiger**

Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont  
Region 4 - Oklahoma, Texas  
Region 9 - New York

#### **Elizabeth Gans**

Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia  
Region 5 - Arizona, California, Nevada, New Mexico, Utah  
Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington

#### **Clifton McClenney**

Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin  
Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming  
Region 10 - Indiana, Michigan, Ohio

#### **William Van Vleck**

Region 3 - Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico  
Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

**In the following proposals, new policy language is underlined. Language that will be deleted has a line through the text. For example, this is how proposed new language will appear and ~~this is how proposed deleted language will appear~~.**

## 1. Proposed Modifications to UNOS Policy 3.6.11 (Allocation of Livers for Segmental Transplantation)

### Summary

The proposed policy change is intended to clarify the sequence of allocation for adult cadaveric livers accepted for segmental transplantation. The proposed modification to the allocation sequence provides a structure for equitably allocating split livers to potential recipients.

### Background

Policy 3.6.11 currently allows a recipient transplant center that elects to split a donor liver broad discretion in allocating any remaining segment to patients on the UNOS liver waiting list. In May 1997, the Liver Committee considered altering the policy, such that segmental livers would be allocated in a more systematic manner, rather than at the discretion of the recipient transplant center. However, at that time, the Committee agreed that the policy should not be modified until a consensus could be achieved on the appropriate procurement and surgical techniques required for segmental transplantation. In 1998, the Split Liver Allocation Subcommittee was appointed to study the feasibility of mandatory splitting of all suitable donor livers on a national basis, and was charged with making recommendations to the Liver and Intestinal Organ Transplantation Committee concerning systems to increase the number of split liver transplants. This Committee drafted a plan for national split liver allocation, which was submitted for public comment and subsequently approved by the Board of Directors in June 1999. However, upon reconsideration of the plan by the Liver and Intestinal Organ Transplantation Committee in July 1999, the Committee identified a number of logistical and operational issues associated with implementation of the arrangement. These issues were referred to the Split Liver Allocation Subcommittee for further consideration. This Committee determined that a national policy governing split-liver allocation was most likely premature, due in part to the limited number of centers that were performing these procedures. A national conference on segmental liver transplantation is scheduled for 2001, after which the Liver and Intestinal Organ Transplantation Committee will assess the recommendations that emerge from the conference. The proposed change in Policy 3.6.11 is intended to clarify and strengthen the existing policy, until such time as a national split liver allocation policy can be developed and implemented.

### Policy Proposal

During a teleconference on May 8, 2000, the Split-liver Allocation Subcommittee of the Liver and Intestinal Organ Transplantation Committee considered the appropriateness of permitting the recipient transplant center discretion for allocating the remaining segment to any candidate on the UNOS liver waiting list, as allowed in Policy 3.6.11. It was suggested that a more appropriate allocation policy for livers offered from outside the OPO would be to require a recipient center that elects to split a liver to return any remaining segment to the Host OPO for allocation to its local waiting list before the liver is allocated elsewhere. It was thought that more livers may be offered for splitting if there is some assurance that a Host OPO's locally waiting patients will have an opportunity to share in the split. Therefore, the Subcommittee proposed the following revisions to Policy 3.6.11:

- 3.6.11 Allocation of Livers for Segmental Transplantation. A transplant center that accepts a liver for segmental transplantation from a Host OPO to which that center is not affiliated, shall offer the remaining segment to the Host OPO for allocation to its local patient waiting list prior to offering the remaining segment to any other medically-appropriate candidates on the UNOS Patient Waiting List. A transplant center that accepts a liver for segmental transplantation from its affiliated Host OPO may allocate the remaining segment to any medically-appropriate candidate on the UNOS Patient Waiting List. If the segment is not allocated for transplantation, it should be offered for other methods of hepatic support as stated in Policy 3.6.10.

This proposal was considered by the Pediatric Transplantation Committee, who offered amendments to the Split-Liver Allocation Subcommittee proposal. The Pediatric Committee did not wish to distinguish between an affiliated versus non-affiliated Host OPO for livers accepted for segmental transplantation. Rather, the liver segment would be allocated in sequence to the highest ranking patient on the waiting list of candidates until and unless it is returned to the original recipient transplant center based upon the limits defined in the policy. The proposal requires the Host

OPO to use reasonable efforts during the procurement process to place the segment(s), which should provide the Host OPO time needed to place the organs if the Host OPO is able to place the organs at all. If it cannot, a procurement team from the original recipient transplant center would typically be available at the donor procurement site and could take all liver segments with it for placement of the remaining segment(s) as it deems most appropriate. The proposal institutes a limit on the time allowed the Host OPO to place available liver segments, intended to ensure that placement of the segments proceeds efficiently, effectively, and with as little wastage as possible. The limit selected by the Committee is defined by the completion of the donor organ recovery procedure, after which the center to whom the whole liver was allocated could use available segment(s) for any appropriate patient. This change to Policy 3.6.11 would parallel language in Policy 3.6 that describes the sequence of allocation for pediatric livers that are preferentially offered to pediatric recipients and subsequently split. The proposal submitted by the Pediatric Committee is as follows:

3.6.11 Allocation of Livers for Segmental Transplantation. A transplant center that accepts a liver for segmental transplantation ~~from a Host OPO to which that center is not affiliated, shall offer the remaining segment to the Host OPO for allocation to its local patient waiting list prior to offering the remaining segment to any other medically appropriate candidates on the UNOS Patient Waiting List~~

- (i) ~~in sequence, as determined by the adult donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers) and defining "local" based upon the Host OPO's local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure is complete, or~~
- (ii) ~~into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure is complete.~~

~~A transplant center that accepts a liver for segmental transplantation from its affiliated Host OPO may allocate the remaining segment to any medically appropriate candidate on the UNOS Patient Waiting List. If the segment is not allocated for transplantation, it should be offered for other methods of hepatic support as stated in Policy 3.6.10.~~

During its January 2001 meeting, the Liver and Intestinal Organ Transplantation Committee discussed the potential impact of these suggestions on the practice of segmental liver transplantation, and it was felt that the proposal drafted by the Pediatric Committee was fair and could encourage the splitting of livers. With one modification, the replacement of the word 'adult' in 3.6.11(i) (as recommended by the Pediatric Committee), with the word 'cadaveric,' the Committee recommends the language proposed by the Pediatric Committee. The removal of the word 'adult' would clarify that the remaining segment should be offered to both adult and pediatric patients. The Committee wanted to ensure that the policy does not restrict allocation of the remaining portion to adults only.

Following a vote of 8 for, 2 against, and 0 abstentions, the Liver and Intestinal Transplantation Committee recommended the following changes to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation), be sent for public comment:

**RESOLVED, that the Liver and Intestinal Transplantation Committee recommends that Policy 3.6.11, be revised as follows:**

**3.6.11 Allocation of Livers for Segmental Transplantation. A transplant center that accepts a liver for segmental transplantation ~~may shall allocate offer the remaining segment to any medically appropriate candidate on the UNOS Patient Waiting List. If the segment is not allocated for transplantation, it should be offered for other methods of hepatic support as stated in Policy 3.6.10.~~**

- (i) in sequence, as determined by the cadaveric donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers) and defining “local” based upon the Host OPO’s local area, to the highest-ranking patient on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure is complete, or
- (ii) into patients listed with the recipient program or any medically appropriate candidate on the UNOS Patient Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure is complete.

**If the segment is not allocated for transplantation, it should be offered for other methods of hepatic support as stated in Policy 3.6.10.**

## **2. Proposed Modifications to UNOS Policy 3.4.6 (Application, Review, Distribution and Modification Processes for Alternative Organ Distribution or Allocation Systems)**

### **Summary**

The purpose of the proposed change to policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems) is to allow submission of applications for variances, sharing arrangements, or alternative local units (ALUs) without unanimous agreement from all participants. The proposal would allow such applications to be submitted with a minimum of 75% participation of the parties involved (e.g., all of the OPOs and transplant centers in a Region). As with all applications for variances, sharing arrangements, and ALUs, such applications would still require approval by the appropriate organ-specific Committee and the UNOS Board of Directors. This policy change would simply permit such proposals to be considered for approval without the requirement for unanimity.

### **Background**

Policy 3.4.6 defines the processes for applying for a new or modified alternative organ distribution or allocation system, review of such systems by UNOS and withdrawal from such systems by any one or more of the participants. The application process is described in policy 3.4.6.1. Presently, a variance application must be supported by each OPO and transplant center that is to take part in the variance prior to approval.

In July 2000, the Liver and Intestinal Organ Transplant Committee reviewed a proposal for the sharing of livers in Region 5. The Committee was informed that the vote on this agreement at the Region 5 meeting was not unanimous; rather, 21 of 26, or 80% of the total number of OPOs and transplant centers in the Region had voted in favor of the agreement. The Region 5 liver sharing agreement plan stipulated that it be adopted and remain in force for one year following approval of 75% of the transplant centers in Region 5. The Committee discussed the importance of having unanimous agreement of the participants on variances, sharing agreements and alternative local units (ALU). However, the Committee agreed that the lack of unanimity seemed in some cases to be extremely difficult to resolve, and that broader sharing of organs could be blocked by a few dissenting centers due to this requirement.

### **Policy Proposal**

By a vote of 9 for, 0 against, and 2 abstentions, the Committee recommended a resolution to the Board of Directors that 3.4.6.1 be changed, subject to public comment, such that applications to allocate livers using either a variance, sharing agreement or ALU for livers need only have approval of 75% of the UNOS member OPOs and or transplant centers. This request was considered at the November 2000 Board of Directors meeting. Members of the Board discussed the fact, in several prior instances, regional sharing arrangements had been considered by the Board without unanimity from the participants. At the time these arrangements were considered, they were seen as case specific modifications of the policy, to be dealt with on an individual basis. The sharing agreements had been

submitted for public comment and were approved by the Board only after review of public comment. This policy change would, in effect, provide a more formalized process by which such applications could be considered. After discussion the Board agreed to submit this proposal for public comment, but modified the language to apply to all organ types. In response to §121.4 of the Final Rule, which requires submission of UNOS policies to DHHS prior to implementation, the Board of Directors also recommended that Policy 3.4.6 be sent to DHHS concurrent with public comment. Also consistent with the Final Rule, the Board approved an additional amendment to the proposal to require that applications for alternative organ distribution or allocation systems address applicable considerations in the Rule.

The Board of Directors approved the following motion during its November 2000, meeting:

**RESOLVED, that UNOS Policy 3.4.6, modified as found below, be approved for submission to DHHS and for public comment concurrently.**

The revised text of Policy 3.4.6, to be submitted for public comment, is as follows:

**3.4.6 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the processes for applying for a new or modified alternative organ distribution or allocation system, review of such systems by UNOS and withdrawal from such systems by any one or more the participants.

**3.4.6.1 Application.** Applications to allocate organs locally using alternate point assignments (variances) may be submitted by OPOs, UNOS Members participating in a UNOS approved ALU or UNOS Members participating in a UNOS approved sharing arrangement. In each case, the application ~~must be supported by~~ indicate for each OPO and transplant center that is to take part in the variance whether or not the institution supports the variance. Applications to distribute organs according to sharing arrangements or ALUs may be submitted by OPOs; any such application must indicate ~~prior approval by~~ for the Board of Directors of each applicant OPO whether or not the OPO's Board of Directors supports the sharing arrangement or ALU, as applicable. Applications to allocate organs using either a variance, sharing agreement or ALU for livers need only have approval of 75% of the UNOS member OPOs and or transplant centers.

Applications to allocate organs using alternate point assignments (variances) or to distribute organs using sharing arrangements or ALUs must be considered by the applicable UNOS Region(s) and by the appropriate UNOS organ-specific committees and Board of Directors. The Board of Directors may refer any such application to additional UNOS reviewing committees as deemed appropriate by the Board. Regional consideration of applications must occur prior to their submission to the Board of Directors and shall include a non-binding vote by the institutional UNOS Membership within the applicable region; this vote and any commentary shall be submitted to the appropriate UNOS committees and Board of Directors for use in their respective deliberations of the application. Applications to distribute organs using an ALU must demonstrate an inequity in organ distribution within the applicable OPO or OPOs and how this inequity is corrected by the ALU without disproportionate harm to any patient population within the local area. The application must, at a minimum, address the following criteria, and how they are expected to be impacted by the ALU: (a) patient waiting time (stratified by patient populations), (b) graft survival (stratified by patient populations), and (c) organ availability.

**Applications shall address the considerations stated in Section 121.8 (a) and (g) of the Final Rule and must comply with other application requirements as may be established by the appropriate UNOS committees and Board of Directors. All alternate point assignments (variances), sharing arrangements and ALUs must be approved by the UNOS Board of Directors and programmed on the UNOS computer prior to implementation. In the case of ALUs, initial approval by the Board of Directors shall be on a provisional basis for a period of 3 years. By the end of this period, the applicable OPO(s) must have demonstrated through objective criteria that the inequity addressed by the ALU has been corrected or at least that improvement to this end has been accomplished. At the end of the provisional approval period, the appropriate reviewing committees will recommend to the Board of Directors that the ALU be: (a) finally approved, (b) approved on a continued provisional basis for a specific period of time, or (c) terminated.**

**When a variance, sharing arrangement or ALU is proposed to permit participation of a distribution unit in a scientific study to test a stated hypothesis with defined parameters under controlled conditions, such a variance, sharing arrangement or ALU may be approved by the Board of Directors for implementation if it (a) is of scientific merit (The Board may consider prior approval of such national agencies as the National Institutes of Health, Veterans Administration or national voluntary health agencies in making this determination); (b) extends for a defined, limited time period not greater than 5 years; and, (c) will have no net effect on the number of organs available for transplant within the applicable distribution unit, or potentially affected larger distribution units which include the applicable distribution unit. Such proposals will be considered in accordance with the standard UNOS process for consideration of variances, sharing arrangements or ALUs, as applicable.**

**(No further changes to 3.4.6)**

### **3. Region 5 Liver Sharing Arrangement and Variance for Status 1 Transplant Candidates**

#### **Summary**

The proposed variance is designed to facilitate the sharing of livers for critically ill patients in Region 5. The variance includes a payback provision, intended to engender trust among the programs in Region 5, who have historically been reticent to share regionally. The variance is time-limited, in that the impact of the variance on organ allocation within the region will be reassessed annually, to be reviewed and reapproved by UNOS. The Region has defined seven measures which will be used to assess the variance: the number of organs shared under the agreement; the survival of recipients; the numbers of deaths waiting in Status 1; the incidence of primary graft non-function; the number of organs not recovered or discarded; the number of payback organ offers declined; and a general review of organs shared and recipients receiving organs under this sharing agreement.

#### **Background**

UNOS Policy 3.6 (Allocation of Livers) was amended by the UNOS Board of Directors on June 24, 1999 to provide for regional liver sharing to Status 1 patients. The revised policy was implemented on August 16, 1999. In approving this policy, the UNOS Board also encouraged all UNOS regions that did not already have regional sharing agreements to develop such arrangements. To assist UNOS regions with developing regional liver Status 1 sharing arrangements, the Board tasked the UNOS Liver and Intestinal Organ Committee to assist the regions in developing systems tailored to regional experience and concerns by exploring the experience of other regions with such arrangements that have been shown to work.

At its July 20, 1999 meeting, the Committee recommended that the liver transplant programs and OPOs in UNOS Regions 2, 3, 5, 6 and 7 initiate a dialogue on developing alternative regional liver sharing arrangements for Status 1 patients. To facilitate this dialogue, descriptions of the arrangements currently implemented in UNOS Regions 1, 4, 8, 9, 10 and 11 were provided. UNOS regional administration and research staffs also were made available to assist and coordinate communication and provide analytical support.

Region 5 began working to develop a Status 1 sharing arrangement in 1999, but has been unable to achieve unanimity within the Region. After significant debate, the Region approved a plan for regional sharing during its October 6, 2000 regional meeting (28 in favor, 8 opposed, and no abstentions). Following the Region 5 meeting, a ballot was mailed to each OPO Executive Director and liver/intestine transplant Program Director in Region 5. A total of 7 OPOs and 14 liver transplant programs voted in favor of this agreement, while one OPO and four liver transplant programs indicated that they would not participate in the proposed sharing arrangement. One transplant program director outlined specific concerns with the proposal in a letter to the Regional Administrator; however, the OPO that serves that center voted to participate in the sharing arrangement. It is not clear that the dissenting programs' votes are an indication that these centers would not comply with the arrangement if implemented. Despite the lack of unanimity, the Region forwarded the proposal to the Liver and Intestinal Transplantation Committee for approval.

On December 7, 2000, the Liver Committee met via teleconference and voted (8 for, 1 against, with 3 abstentions) that the sharing agreement be approved and forwarded to the Executive Committee of the Board for final approval. The Executive Committee met via teleconference on January 16, 2001, and, after deliberation, agreed to approve the proposed variance. Historically, sharing arrangements with variances have been subject to a requirement for 100% participation by all parties in the allocation unit, and some concern was expressed regarding the lack of unanimity. However, it was noted that the Board of Directors voted in November, 2000, to allow applications for variances/sharing arrangements to be considered if a minimum of 75% of the participating OPOs and transplant centers are in agreement. That proposal had been forwarded to the Board of Directors by the Liver and Intestinal Organ Transplantation Committee because of this particular situation (the lack of unanimity in Region 5), and had been approved by the Board subject to public comment. Another concern expressed during the teleconference was that, in accordance with §121.8 (g) of the OPTN Final Rule, variances for organ allocation "shall be accompanied by a research design and include data collection and analysis plans" and must be time-limited. The Executive Committee asked that the Region ensure that these provisions of the Final Rule are met by the variance application.

### **Policy Proposal**

The sharing arrangement is similar to the one in place in Region 7, and is included in Exhibit A\*. The proposal includes a payback provision, with a limit to the number of livers that can go out of an OPO without a payback coming in. OPOs that accumulate four (4) debts would be required to pay back the next liver, unless there is a local Status 1. An OPO with 4 debts and a local Status 2A patient would be required to pay back the next liver, even if the organ would be transplanted into a Status 2B or 3 patient by the center accepting the liver for payback. Thus, each OPO can accumulate 3 debts before having to payback the next local liver in lieu of using it for a local Status 2A. This provision should provide some impetus to reduce payback debt. Another stipulation of the proposed plan is that, if an OPO "receives a shared liver and an arrangement is made with the Host OPO to perform a Left Lateral Segment Split, where the accepting OPO only uses the segment and leaves the remainder of the liver for the Host OPO, then the accepting OPO would not accrue a debt. This provision could potentially encourage the splitting of livers. Finally, this arrangement should resolve difficulties within Region 5 arising from a law passed by the State of Arizona requiring that Arizona-procured livers be offered to Arizona recipients only, unless a reciprocal agreement for sharing could be created.

**The motion approved by the Executive Committee, to be circulated for Public Comment, is as follows:**

**RESOLVED, that the proposed Region 5 sharing arrangement and variance agreement for Status 1 liver candidates be approved for immediate implementation, subsequent to system programming, and concurrent with Public Comment. The Region is expected to submit a study plan in keeping with the provisions in the Final Rule within 30 days.**

#### **4. Proposed Modifications to UNOS Policies 3.5.2.4 (Kidney/Non-Renal Exceptions), 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates), and 3.8.1 (Pancreas Organ Allocation)**

##### **Summary**

This policy proposal applies to allocation of zero antigen mismatched kidney/pancreas combinations. It would eliminate requirements for sharing kidney/pancreas combinations for zero antigen mismatched patients unless the patient is highly sensitized (*i.e.*, panel reactive antibody (PRA) greater than or equal to 80%). It is proposed in light of current data that no longer show significant benefit in terms of short-term or long-term kidney or pancreas graft survival from receipt of a zero mismatched versus mismatched kidney/pancreas transplant. The policy would be retained for highly sensitized patients due to difficulties for these patients in getting transplanted at all.

In developing this proposal, transplant outcomes for recipients of zero antigen mismatched isolated kidneys also were examined. For these patients, a significant benefit continues to exist. Transplant outcomes for recipients of payback kidneys were assessed as well to determine if the system for sharing zero antigen mismatched kidneys is indirectly creating a negative impact due to relatively poor results from kidneys shared back to the national donor pool following receipt of these organs. Recipients of payback kidneys appear to experience at least as good transplant outcomes as do recipients of other kidneys. No further changes in policy are, therefore, being recommended at this time.

##### **Background**

A Subcommittee of the Kidney and Pancreas Transplantation Committee has, since 1998, been studying various issues regarding equity and human leukocyte antigen (HLA) mismatch level in kidney and pancreas allocation. Among the issues being examined is whether there continues to be significant benefit for recipients of zero antigen mismatched kidneys and kidney/pancreas combinations in terms of improved graft survival and access to transplantation for highly sensitized patients. Additionally, if there is continued benefit, is the benefit abrogated by relatively poor transplant outcomes for recipients of payback kidneys?

UNOS policy for allocating kidneys presently requires that kidneys for whom there is one or more “optimally” matched patients on the waiting list must be shared for these patients before they can be shared for other patients listed for transplantation. The policy includes an exception for kidneys offered with non-renal organs. An “optimal match” is defined as a six antigen match (*i.e.*, match between donor and recipient where the recipient is matched on all six HLA – A, B, and DR antigens), phenotypic identity between the donor and recipient with regard to HLA - A, B, and DR antigens where at least one antigen is identified at each of the A, B, and DR loci, and all other zero antigen mismatches. Additionally, kidney/pancreas combinations from donors for whom there is one or more “optimally” matched kidney/pancreas recipient on the waiting list must be shared for these patients before they can be allocated to other patients listed for combined kidney/pancreas or either of the isolated organs. A kidney shared for an “optimal” match generates an obligation to pay back a kidney from a donor of the same blood type as the shared organ. The intent of the policies is to improve kidney transplant outcomes as a result of superior graft survival rates from zero antigen mismatched kidney transplants, and increase opportunities for transplanting highly sensitized (*e.g.*, PRA greater than or equal to 80%) patients based upon HLA match and low probability of a positive crossmatch. The policy for combined kidney/pancreas transplants was intended further to encourage multiple organ retrieval and ensure that pancreases not be wasted when offering a donor kidney for a zero antigen mismatched patient who needs a pancreas also.

*Isolated Kidney:* The Subcommittee has concluded that there continues to be a significant benefit for recipients of zero antigen-mismatched kidneys in terms of improved graft survival. This benefit appears to be quantified at approximately 5% - 7% over the long-term, and of most value to the highly sensitized patient for whom a zero antigen mismatch between donor and recipient may be the only realistic option for getting transplanted. This is demonstrated by a multivariate analysis that controls for various donor and recipient factors generally recognized as having an effect on graft survival (*e.g.*, donor and recipient age, ethnicity, gender, previous transplant, diagnosis, etc.), and compares graft survival depending on the match level of the kidney and whether the organ was used

locally or was shared with another OPO (Exhibit B\*). Kidney alone transplants between July 1, 1993 – June 30, 1996 were examined using the following groups:

Group	Number of Transplants
0 MM – Local	198
0 MM – Shared	827
6 Ag Match – Local	57
6 Ag Match – Shared	1,095
Phenotypic Identical – Local	34
Phenotypic Identical – Shared	413
Other MM - Local	15,155
Other MM – Shared (Voluntary)	3,432
Other MM – Shared (Payback)	1,101

Using other mismatch local transplants as the reference group, the analysis shows at least marginally significantly reduced odds of three-year graft failure for each group of mandatory share well matched kidneys (*i.e.*, the first six groups listed above), except six antigen match local.

The benefit in long-term outcome also is shown by an analysis of mandatory shared kidneys with the donor’s other kidney, when the second kidney was not a mandatory share, using 767 donors between July 1, 1993 and June 30, 1996. At three years following transplant, 83% of the kidneys in the mandatory share group were still functioning and 78% of the donors’ other kidneys were still functioning. This difference was found to be statistically significant at  $p < 0.01$  using McNemar’s test.

The benefit in terms of improved outcomes from receipt of kidneys shared on a mandatory basis due to mismatch level still exists when the group of transplants studied includes only transplants between March 6, 1995 and December 31, 1998. (March 6, 1995 was chosen as the start date for this cohort as it was the date the definition of mandatorily shared kidneys in UNOS policy changed from six antigen match to zero antigen mismatch.) This is shown by a multivariate Cox regression analysis of 27,117 cadaveric kidney transplants with known HLA match level and follow-up data, including 4,236 transplants in the zero mismatch category, 18,214 transplants in an other mismatch local category, and 4,667 transplants in an other shares category (Exhibit C\*). Compared to the zero mismatch transplants, the non-zero mismatch local transplants and transplants from the other shares category had a significantly increased likelihood of graft failure.

The analyses also demonstrate that the risk of kidney graft failure increases progressively at each level of HLA mismatch. For example, in a multivariate Cox regression analysis of 33,138 kidney alone transplants between March 6, 1995 and June 30, 1999, the risk of graft failure increases from 1.19 for a HLA mismatch level of 1 versus 0 to 1.54 for a HLA mismatch level of 6 versus 0 (Exhibit D\*). This result is shown in the following table of HLA mismatch level and the associated risk ratios and p-values.

HLA Mismatch (MM) Level	N	Risk Ratio	p-value
Phenotypic Identical	2254	1.000	--
Other 0 MM	2959	1.000	--
1 MM	1155	1.188	0.030
2 MM	3897	1.189	0.001
3 MM	7468	1.206	<0.001
4 MM	7747	1.344	<0.001
5 MM	5187	1.371	<0.001
6 MM	2471	1.535	<0.001

The Subcommittee reviewed transplant outcomes from zero antigen mismatched kidney transplants specifically for highly sensitized (*e.g.*, PRA  $\geq$  60% or 80%) recipients of kidney transplants. These kidneys present the most realistic opportunity for getting this group of patients transplanted. Potential recipients who have been exposed to

the HLA antigens of another individual as a consequence of pregnancy, blood transfusions, or previous transplantation are at risk of developing antibodies against foreign HLA antigens. Due to this sensitization, they reject kidneys from the majority of donors. A zero antigen mismatch between donor and highly sensitized patient presents the best chance for avoiding rejection based upon these biological factors. A large donor pool that provides greater opportunities for locating such matches can, therefore, be of particular benefit to sensitized patients.

The Subcommittee reviewed the univariate analyses in Exhibit E\*, assessing cadaveric kidney transplants performed between March 6, 1995 – June 30, 1999. Table E-1A again confirms the Subcommittee's prior conclusion that recipients of zero antigen mismatched kidney transplants continue to experience significantly improved short-term and long-term graft survival compared to recipients of mismatched kidneys. At three years post transplant the difference in outcomes is approximately 6%. Table E-1C shows consistently improved outcomes for the zero antigen mismatched recipient in the case of White and Black patients. For Hispanic and Asian patients, there is some trend in this regard, although the overlap in 95% confidence intervals indicates that the differences in outcomes may not be significant.

Table E-2A (also see Table E-4) shows that almost half (383 of 831 or 46%) of the highly sensitized patients (defined as PRA  $\geq$  80%) transplanted during the study period received zero antigen mismatched transplants. This represented 7.4% of the 5,211 zero antigen mismatched kidney transplants overall. Highly sensitized patients represented even smaller percentages of those patients receiving mismatched kidney transplants. Table E-2B shows that the percentage of highly sensitized patients within the various ethnic populations varied from a low of 1.4% in the Asian patient population to a high of 2.9% in the White patient population.

Table E-3 shows overall kidney graft survival by patient PRA levels. Those patients with PRA  $\geq$  80% experienced the worst survival at 1, 2, and 3 years following transplant, although there is some overlap in 95% confidence intervals. Table E-5A shows that these outcomes are not influenced by level of HLA mismatch between donor and recipient. That is, highly sensitized patients experienced similar graft survival whether they are transplanted with zero antigen mismatched kidneys or mismatched kidneys.

A similar result of relative poor graft survival for sensitized patients was also seen in a multivariate Cox regression analysis of kidney alone cadaveric transplants performed between March 6, 1995 – June 30, 1999 (Exhibit F\*). This model showed that for patients with PRA between 10%-79%, the risk of graft failure was 27% higher than for patients with PRA less than 10%. For those patients with PRA 80% or greater, the risk of graft failure was 60% greater than for those patients with PRA less than 10%.

It appears, therefore, that highly sensitized patients do benefit from the zero antigen mismatch kidney sharing policy in terms of access to transplantation. Receipt of these well matched kidneys does not, however, result in significantly improved graft survival for this group of patients.

*Payback Kidneys:* The requirement for “paying back” a kidney to the system upon receipt of a zero antigen mismatched kidney (when shared from an outside OPO) is intended to address disparities in the distribution of the “optimally” matched kidneys. It can accomplish this objective only if the kidneys used to satisfy payback debts function relatively well. To address this issue, the Subcommittee reviewed a multivariate analysis of 19,688 kidney alone transplants between July 1, 1993 and June 30, 1996 comparing graft survival for kidneys used locally, shared for other than payback, and shared for payback (Exhibit G\*). The analysis shows no significant difference in three-year graft survival for either of the share groups. Additionally, outcomes of the voluntarily shared kidney transplants are not statistically different from the outcomes of kidneys used for payback. This result also is demonstrated by an analysis of payback kidneys with the donor's other kidney, when the second kidney was not a payback kidney, using 520 donors between July 1, 1993 and June 30, 1996. At three years following transplant, 75% of the payback kidneys were still functioning and 76% of the donors' other kidneys were still functioning. This difference was not found to be statistically significant at  $p=0.41$  using McNemar's test. Finally, the result is confirmed by a Kaplan-Meier analysis of payback kidneys, locally used kidneys, and voluntarily shared kidneys. The Subcommittee concluded, therefore, that the system of requiring a payback for kidneys shared on a mandatory basis (with the intent of maximizing transplant outcomes) does not appear to jeopardize graft survival for the recipients of these payback kidneys.

In discussing these analyses, the Subcommittee noted that outcomes, particularly for transplanted payback kidneys,

might be affected by the recipient transplant program's ability to accept only those kidneys deemed suitable to the program. The debt will continue to be owed until an organ considered acceptable is offered. Programs may, therefore, demand that payback kidneys meet relatively high quality standards. It might be expected that these kidneys would survive longer. In an effort to study this further, the Subcommittee has reviewed characteristics of payback kidneys versus other kidneys used in the analyses. The Subcommittee continues to conclude that outcomes of payback kidneys are similar to other non-zero mismatch kidneys.

Importantly, both the systems for sharing "optimally" matched kidneys, as well as the system for allocating payback kidneys of the same blood type to the pool of available kidneys, contribute to disassociating candidate place of listing (residence) with distribution/allocation. In each case, organs are allocated to patients who meet specified criteria and who are listed for transplantation anywhere in the country before they are offered for other patients locally. In the case of zero antigen mismatched organs, patient eligibility is defined by factors such as HLA match, blood group, and sensitization. In the case of payback kidneys, patient eligibility is defined by factors such as blood group and time debt has been owed. There is, therefore, no direct reciprocity between transplant centers or even OPOs in the allocation of payback kidneys. Each of the systems expands the geographic area over which organs are distributed.

*Combined Kidney/Pancreas:* For combined zero antigen mismatched kidney/pancreas transplants, the Subcommittee determined that differences in transplant outcomes comparing "optimally" matched recipients with mismatched recipients no longer warrant continuation of a policy requiring sharing of combined kidneys/pancreases for these "optimal" matches. The intent of the policy for allocating a donor kidney together with the donor pancreas for zero antigen mismatched patients was to ensure that the pancreas not be wasted when offering a donor kidney for a zero antigen mismatched patient who also needs a pancreas. This should encourage multiple organ retrieval and maximize graft survival due to (at least historical) superior results for recipients of zero antigen mismatched combined kidney/pancreas, isolated kidney, and isolated pancreas transplants. For combined kidney/pancreas transplantation, benefits from HLA matching were shown only at the highest level of match (*i.e.*, a zero antigen mismatch with the donor). With the exception of allocation of the kidney with the pancreas from a single donor in the case of zero antigen mismatched patients, allocation of kidney/pancreas combinations versus the kidney and pancreas alone is discretionary at the local level of organ distribution and invokes an obligation to pay back the kidney when shared at the regional or national levels of distribution.

The Subcommittee has noted that increased costs and cold ischemia time may have different impacts in the allocation of pancreases versus kidneys due to the relatively short time pancreases can remain viable for transplantation without oxygenated blood. Moreover, as with allocation of isolated zero antigen mismatched kidneys, impacts from the policy for allocating zero antigen mismatched kidney/pancreas combinations that may be unique to highly sensitized patients must be considered.

At its September 19, 2000 meeting, the Subcommittee reviewed the univariate analysis of cadaveric transplants performed between March 6, 1995 – June 30, 1999 shown in Exhibit H\*. Table H-1 reports volume, by HLA mismatch level, of pancreas alone, simultaneous kidney/pancreas, and pancreas after kidney transplants performed during this period. Of the 3,909 simultaneous kidney/pancreas transplants, 108 (or 2.8%) were zero antigen mismatched. Tables H-3A and 3B report survival rates for both the pancreas and kidney associated with these transplants. While the volume of transplants, and, therefore, power in this analysis is not great, survival rates for both organs do not appear to be greater than the survival rates of mismatched kidneys and pancreases transplanted in combination. This is consistent with data reviewed by the Subcommittee based upon an older but larger cohort of transplants.

Table H-6B shows the relationship of pancreas graft survival by HLA mismatch level and pancreas preservation time for the combined kidney/pancreas transplants performed during the study period. In a number of cases there was insufficient data to calculate a survival rate. In the zero mismatched transplants, there was no difference in the survival at one year between those with cold ischemia time of 0 – 12 hours and those with cold ischemia time of 13 – 24 hours.

Table H-7 shows combined kidney/pancreas transplants, by recipient PRA and level of mismatch between donor and recipient. Of the 3,908 total kidney/pancreas transplant procedures, 24 or 0.6% were performed in highly sensitized patients. Of these, 3 (or 12.5%) were zero antigen mismatched.

Finally, Exhibit I\* again confirms that risk of kidney or pancreas graft failure in combined kidney/pancreas recipients is not significantly associated with antigen mismatch level for kidney/pancreas recipients transplanted between March 6, 1995 – October 31, 2000. Exhibit I\* shows the relative risk of kidney and pancreas graft survival in recipients receiving simultaneous kidney/pancreas transplants versus level of HLA antigen mismatch. The study used a Cox regression analysis adjusted for primary diagnosis; PRA; donor cause of death; and donor and recipient race, ethnicity, sex, and age.

## **Policy Proposal**

The Subcommittee concluded that there no longer appears to be any significant benefit in terms of short-term or long-term kidney or pancreas graft survival from mandatory sharing of zero antigen mismatched combined kidneys/pancreases. It was noted that the original focus of this policy was on maximizing procurement and use of donor pancreases rather than on improving graft survival. Subcommittee members commented, however, that, in practice, pancreases offered regionally or nationally are seldom accepted. The expectation that these organs will be recovered in light of this policy and anticipating opportunities for placement may not be realistic. The Subcommittee also discussed the unique situation for highly sensitized patients. Due to the relatively low likelihood that these patients will receive transplants of any mismatch level, there would be some benefit for this group of patients in maintaining the policy as applied to them only. The number of zero antigen kidney/pancreas transplants performed in highly sensitized patients during the period March 6, 1995 – June 30, 1999 was small at only 3. Maintaining the sharing policy for these patients alone should, therefore, reduce any burdens imposed by this policy while maintaining some potential benefit for the group of patients who may have the most to gain from receipt of a zero antigen mismatched organ offer.

The Subcommittee, therefore, voted unanimously to approve the following recommendation:

**RESOLVED, that the following proposed modifications to UNOS Policies 3.5.2.4 (Kidney/Non-Renal Exception), 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates), and 3.8.1 (Pancreas Organ Allocation) shall be distributed for public comment, subsequent reconsideration by the Kidney and Pancreas Transplantation Committee, and final recommendation to the Board of Directors:**

**3.5.2.4 Kidney/Non-Renal Exception. When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched patients. This exception does not apply to kidney-islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized patients as defined in Policy 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).**

**3.5.3 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, “highly sensitized” is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.**

**3.5.3.1 Mandatory Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.**

**3.8.1 Pancreas Organ Allocation.** For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a patient on the UNOS Patient Waiting List who meets the requirements of Policy 3.5.3 or Policy 3.8.1.6 and for whom there is a zero antigen mismatch with the donor. Within each Patient Waiting List, length of time waiting shall be considered for the selection of organ recipients. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5.3. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.3, the pancreas shall be allocated regionally and then nationally, or for patients listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence:

**3.8.1.1 Regional Whole Pancreas Allocation.** [No Changes]

**3.8.1.2 National Whole Pancreas Allocation.** [No Changes]

**3.8.1.3 Facilitated Pancreas Allocation.** [No Changes]

**3.8.1.4 Islet Transplantation.** [No Changes]

**3.8.1.5 Islet Allocation Protocol.** [No Changes]

**3.8.1.6 Mandatory Sharing of Zero Antigen Mismatch Pancreata.** In the event there is a patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate UNOS member for any highly sensitized patient waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.3 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then be offered to the appropriate UNOS member for any patient waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a patient listed on the Host OPO's local patient waiting list for combined kidney/pancreas or isolated pancreas transplantation who has panel reactive antibody (PRA) level of 80% or greater based on historical or current serum samples, as used for crossmatch to determine suitability for transplant, and there is a negative preliminary crossmatch between the donor and that patient. In this event, for local allocation, the pancreas shall be offered for the patient(s) with PRA greater than or equal to 80% and a negative preliminary crossmatch (based upon length of time waiting if more than one patient meets these criteria) before being offered for zero antigen mismatched isolated pancreas transplant candidates.

**3.8.1.6.1 Time Limit.** [No Changes]

Following discussion, this recommendation was approved by the full Kidney and Pancreas Transplantation Committee on October 26, 2000, by a vote of 13 For; 1 Against; and 1 Abstention. Throughout deliberation of this entire subject, the Subcommittee and Committee have discussed whether PRA greater than or equal to 80% remains the most appropriate level for defining highly sensitized patients. Instead, a level at or around 50% (indicating likely compatibility for only 50% of available kidneys) may more adequately address needs of the highly sensitized. A more comprehensive approach may be to define highly sensitized by a combination of PRA level and time waiting. The Subcommittee and Committee will continue to assess this matter in its application to kidney and kidney/pancreas allocation overall. With respect to the present policy modification, the current definition of PRA greater than or equal to 80% will be continued.

The full Committee also discussed concerns regarding effects of this proposal on diabetic patients waiting for combined kidney/pancreas transplants. In general, diabetics experience higher mortality on the waiting list than non-diabetics, whether listed for isolated kidney or kidney/pancreas transplants. For example, the following table

shows reported deaths on the kidney waiting list, by diagnosis at listing, for the period January 1997 – December 1999<sup>1</sup>:

Diagnosis	<u>No. Deaths Reported</u>	<u>No. Patients</u>	<u>Death Rate (No. Deaths/No. Patients)</u>
All Others	4,747	64,795	7.3%
Type I Diabetes	1,207	8,103	14.9%
Type II Diabetes	1,534	12,296	12.5%
Overall	7,488	85,194	8.8%

Elimination of the preference for allocating the kidney with the pancreas for zero antigen mismatched combined kidney/pancreas patients would not eliminate opportunities to use the organs together for a single (diabetic) recipient. The organs could still be placed in combination at the local level or as a voluntary sharing arrangement at the regional or national levels. Moreover, the organs, even if placed individually, could result in transplanting a diabetic patient in need of kidney transplantation due to the significant numbers of diabetic patients listed for isolated kidney transplantation. Committee members suggested that issues regarding medical necessity for kidney transplantation in general are evolving based upon recent data showing mortality while waiting for transplantation versus survival with a transplant. These matters will require attention into the future. The current proposal should not, however, impact organ availability for diabetic patients overall. Instead, it eliminates the need to share these organs broadly for the “optimally” matched patients based upon data showing that a graft survival benefit based upon level of HLA mismatch no longer exists. The organs would still be available for transplantation into diabetic patients waiting at the local or other levels of distribution for an isolated kidney and/or combined kidney/pancreas.

## **5. Proposed New UNOS Policy 3.5.10 (Choice of Right Versus Left Donor Kidney)**

### **Summary**

This proposal would establish a general rule specifying who may select between donor kidneys, when both the right and left kidney are available for transplantation. It is intended to clarify in policy what the Kidney and Pancreas Transplantation Committee believes to be actual practice in this area.

### **Background**

UNOS policy does not address, in general, who has the option of selecting the right or left kidney from a donor, assuming both are available, the surgeon who procures the organs for the Host OPO or the surgeon/physician who is offered the organ for his/her patient based upon priority on the waiting list. Policy provides direction only in the case of zero antigen mismatched organs under Policy 3.5.2.3 (Mandatory Sharing). In this instance, the policy allows the Host OPO to choose among right or left kidney. Silence in the policies in other instances might suggest that leaving these decisions to the Host OPO in the case of zero antigen mismatched kidneys is the exception to the rule – the general rule being that the transplant center receiving the kidney offer has the option to choose among donor kidneys if both are available.

At its October 26, 2000 meeting, the Kidney and Pancreas Transplantation Committee considered an inquiry from an OPO representative regarding the policy for choice of right versus left kidney for non-zero antigen mismatched organs.

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<sup>1</sup> Based on OPTN data as of October 8, 2000. Data subject to change due to future data submission or correction.

## Policy Proposal

Some Committee members noted their understanding that, in practice, the choice between donor kidneys is at the discretion of the physician or surgeon accepting the organ on behalf of a patient based upon the patient's priority on the computer match run. A member noted, however, that this is not universally true. In his local area, for example, selection is based upon a protocol that removes these decisions from the physicians and surgeons. Additionally, offers of a kidney with the donor pancreas or other organ may complicate the right versus left kidney selection process or, at least, invoke slightly different rules.

The Committee determined that policy should be developed to clarify what the Committee believes to be the general practice in this area. The Committee, therefore, voted unanimously to approve the following recommendation:

**RESOLVED, that the following new UNOS Policy 3.5.10 (Choice of Right Versus Left Donor Kidney) shall be distributed for public comment, subsequent reconsideration by the Kidney and Pancreas Transplantation Committee, and final recommendation to the Board of Directors:**

**3.5.10 Choice of Right Versus Left Donor Kidney. Except in the case of donor kidney(s) offered for zero antigen mismatched patients under Policy 3.5.2 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) or for kidney and non-renal organ transplantation, if both kidneys from a donor are transplantable, the recipient center offered a kidney for a patient based upon priority on the waiting list selects which of the two kidneys it will receive.**

**3.5.1011 Broad and Split Antigen Specificities. [No Further Changes.]**

**3.5.1012 Local Conflicts. [No Further Changes.]**

**3.5.1013 Allocation of Cadaveric Kidneys with Discrepant HLA Typings. [No Further Changes.]**

## 6. Proposed Modifications to UNOS Policy 3.5.9.6 (Donation Status)

### Summary

This proposal would allow transfer of points assigned to a former donor for donation status to the original recipient of the donor's organ or organ segment. It is intended to further advance awareness of and focus upon the need for organ donation.

### Background

Policy 3.5.9.6 (Donation Status) currently assigns 4 points to individuals who have actually donated a vital organ or segment of a vital organ for transplantation and who subsequently develop renal insufficiency and need for a kidney transplant themselves. The intent of the policy is to increase awareness of and focus upon the need for organ donation, while acknowledging the sacrifice made by those persons who have served as actual living donors.

At its January 25, 2001 meeting, the Committee considered a request from an individual who had donated a kidney to his son. The father has now been evaluated for kidney transplantation and has been determined to be a qualified candidate. The son, who was the recipient of the father's donated kidney, also has been evaluated for kidney transplantation and determined eligible for re-listing for a repeat transplant. The father requests transfer of the 4 points for donation status he will receive under Policy 3.5.9.6 to his son.

### Policy Proposal

Presently, there is no mechanism in UNOS policy to allow such a transfer. The Committee discussed the possibility of allowing the former donor to assign his/her points for donation status to anyone on the waiting list. This might seem appropriate in recognizing that the act of organ donation itself is a selfless act. The donor may wish, therefore, to share the points assigned for this act just as he/she originally shared an organ. Concern was expressed, however,

that this could establish a precedent for allowing the transfer of other points assigned in the allocation algorithm with unintended harmful consequences. Presently, points are assigned to patients based upon their individual characteristics and for specific purposes. For example, points are assigned if a patient's panel reactive antibody (PRA) level exceeds a particular threshold to address difficulties encountered by these patients in access to transplantation, and priority is assigned based upon human leukocyte antigen (HLA) matching to improve recipient transplant outcomes and utility of donated organs. There is, therefore, a medical/scientific basis for the assignment of points to individuals that could be defeated if these individuals were to be given discretion to transfer them.

The Committee limited its discussion, therefore, specifically to the possible transfer of points for donation status only. There remains some concern that this still could result in unintended harm. Points are awarded under the policy for having been a prior donor not as compensation for the act, but to acknowledge the gift and the possibility that the donor may subsequently himself/herself become dependent upon a transplant perhaps as a result of the gift. To permit transfer of these points to any individual irrespective of a medical/scientific basis for the transfer could appear arbitrary and without appropriate justification.

The Committee determined, instead, that in addition to limiting any option for transferring points to those assigned for donation status only, the proposal also should restrict the potential beneficiary of these transferred points to the original recipient of the former donor's organ or organ segment only. This would focus the option narrowly upon the individual who received the donor's original gift, affording the donor opportunity to continue his/her act of giving in the spirit of this gift. The basis for such transfer would be to further support the donative intent underlying the donation and resulting in assignment of 4 points. The revision to restrict potential transferees of donation status points to the original recipient of the donor's organ or organ segment was approved by a vote of 10 For; 4 Against; and 0 Abstentions.

The Committee believes that the proposal would continue to advance awareness of and focus upon the need for organ donation, consistent with the intent of the Policy 3.5.9.6. The Committee recommends immediate implementation of the proposal and subsequent distribution for public comment to most effectively address the request of the individual donor who brought this issue to the Committee. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors and interim action by the Executive Committee, as feasible:

**RESOLVED, that the following modifications to UNOS Policy 3.5.9.6 (Donation Status) shall be approved for implementation pending programming on the Computer System, and simultaneously distributed for public comment, subsequent reconsideration by the Kidney and Pancreas Transplantation Committee, and final recommendation to the Board of Directors following consideration of public comment:**

**3.5.9.6 Donation Status. A patient will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.9.6, the patient's physician must provide UNOS with the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other patient information required to be submitted under UNOS policy. A patient determined eligible for receipt of 4 points for donation status, as defined above, may retain these points for determining his/her own priority for allocation of donated kidneys in the event of subsequent renal insufficiency and qualification as a transplant candidate, or transfer them to the recipient of the donated organ or organ segment in the event the recipient is re-listed for kidney transplantation.**

Committee Vote: 8 For; 6 Against; 0 Abstentions

## **7. Proposed Call for Participation by OPOs in a Local Voluntary Renal Allocation Variance for Transplantation of Blood Group A<sub>2</sub> and A<sub>2</sub>B Cadaveric Kidneys into Blood Group B Waiting List Candidates**

### **Summary**

The proposed national voluntary variance is intended to provide a clinical framework for testing the efficacy of transplanting A<sub>2</sub>/A<sub>2</sub>B kidneys into blood group B recipients. Additionally, it is expected that the proposed renal allocation variance will increase the availability of donor organs for blood group B candidates.

### **Background**

UNOS Policies 3.1.9 (Alternate Point Assignment (Variance)) and 3.4.6. - 3.4.6.4 (Application, Review Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems) define a process and pathway for application for a new or modified alternative organ distribution or allocation system other than that imposed in policy. Historically, OPOs have utilized variances as a means of allocating organs in participating local or regional units using alternate point assignments to better meet the specific needs and demands of its local patient population. The variance must be supported by each OPO and transplant center that will take part in the alternate allocation system and undergo a rigorous and thorough process of review and public scrutiny prior to receiving approval of the UNOS/OPTN Board of Directors. Variances are intended to be provisional for a finite period and must demonstrate throughout its life scientific merit as well as not to have an adverse effect upon the number of organs otherwise available for transplant.

At its March 6-7, 2000 meeting, the Minority Affairs Committee voted to propose a national voluntary variance that would permit the transplantation of A<sub>2</sub> and A<sub>2</sub>B kidneys into B recipients. Over time, the Committee has noted significant increases in waiting time for blood group B candidates compared to candidates of other blood groups, and increasing disparity in the number of minorities receiving kidney transplants compared to Caucasians. This concern and the fundamental mandate under which this Committee functions has led them to follow the progress of pioneers in renal transplantation who were utilizing improved clinical methods to transplant across ABO barriers.

Historically, the requirement for ABO compatibility in renal allocation policy has been found to present a significant barrier to renal organ access for minority candidates, especially for blood group B candidates. UNOS data show that blood group B candidates comprise 17.2% of the national wait list, have access to 11.5% of cadaveric kidney donors and receive 12.5% of cadaveric transplants. In contrast, blood group A candidates who comprise 27.9% of the national waiting list, have access to 38% of the cadaveric kidney donors, and receive 38.5% of the cadaveric transplants. On the renal waiting list, African Americans also have a higher representation of blood group B (48% compared to 32% for Caucasians). Additionally, 68% of the national blood group B wait list is comprised of minorities (See Attached Variance in Exhibit J\*). The 1999 Annual Report of the U.S. Scientific Registry for Transplant Recipients and the Organ Procurement and Transplantation Network reveals that the median waiting time for blood group B candidates added in 1995 was 1225 days compared to 535 days for blood group A and 248 days for AB recipients. Over the life of the OPTN, it has been demonstrated that patients from either blood group B or O are at a disadvantage when faced with the availability of those blood groups in the donor population.

Over the past ten years, Christopher F. Bryan, Ph.D., of the Midwest Transplant Network (formerly Midwest Organ Bank, Inc.) and Douglas J. Norman, M.D., of the Laboratory of Immunogenetics and Transplantation, Oregon Health Sciences University, have reported on their respective centers' successful use of A<sub>2</sub> and A<sub>2</sub>B kidneys for blood group O and B recipients<sup>2</sup>. Most recently, these groups were joined by the Texas Organ Sharing Alliance (TOSA), whose request for a Kidney Allocation Variance to allocate blood group A<sub>2</sub> and A<sub>2</sub>B donor kidneys to blood group B and O patients was approved at the June 15-16, 2000, UNOS/OPTN Board of Directors meeting.

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<sup>2</sup> Bryan CF, et al. Ten-year experience in transplantation of A<sub>2</sub> kidneys into B and O recipients. *Transplantation* 1998; 65: 256

Transplantation across ABO barriers has been performed as early as 1955 with varying success rates. Hume *et. al.* reported on utilization of this subtype of cadaveric donors in 1955<sup>3</sup>. In the early 1960's, Starzl *et. al.* reported on outcomes based on his use of A<sub>2</sub> renal organs, again with varying degrees of success<sup>4</sup>. However, beginning in the late 1980s, Brynager and colleagues were reporting that blood group A donor organs subtyped as group A<sub>2</sub> could be successfully transplanted into non-A recipients and that this could be done without modification of the recipient's immune status before transplantation<sup>5</sup>. By 1995, K. Takahashi *et. al.* published their experiences with ABO-incompatible renal transplantation, which showed that graft and patient survival rates were comparable to those of ABO-compatible kidneys<sup>6</sup>. Increasingly, over the years more and more transplant practitioners have reported successful transplantation of A<sub>2</sub> renal organs into blood group B and O candidates. This type of subtyping for renal transplantation for B and O recipients has been found to be most successful in patients with low anti-A titers. The A<sub>2</sub> subtype kidneys are found in 15% to 20% of the A kidneys. The expression of the A antigen is much less on A<sub>2</sub> red cells as opposed to A<sub>1</sub> red cells and does not induce an agglutination reaction when exposed to anti-A reagents.

The Minority Affairs Committee believes that published data offered by the Midwest Transplant Network and others support the need for a larger standardized study to fully evaluate the viability of this type of transplantation and the benefits it may offer to blood group B renal candidates. At the March 6-7, 2000, meeting, the Chair appointed a subcommittee chaired by Smita Vaidya, Ph.D., At Large representative and Director of the Tissue Antigen Laboratory of the University of Texas Medical Branch, to develop a proposal for a voluntary variance to be presented to the OPTN Board of Directors for approval.

In addition to Dr. Vaidya, the subcommittee included the following medical scientist and UNOS staff: Christopher F. Bryan, Ph.D.; UNOS Research Staff: Alan Ting, Ph.D., Wida Cherikh, Ph.D., Ann Harper; UNOS Information Technology Department: Karen Williams; UNOS Organ Center Supervisors: Roger Brown and Judy Morrisson; and Allocation Policy Department staff, Marcia Manning.

### **Policy Proposal**

The OPTN Minority Affairs Committee believes that in light of the increasing clinical success demonstrated by those OPOs with approved variances to transplant A<sub>2</sub> and A<sub>2</sub>B renal organs into B recipients, timing is opportune to provide a mechanism for other OPOs to participate in a national standardized study that would yield valuable clinical information regarding this method of organ allocation. The Committee believes that transplantation of A<sub>2</sub> and A<sub>2</sub>B renal organs into blood group B recipients has the potential to result in the following:

- Transplantation of a greater number of blood group B candidates by expanding their potential donor pool;
- An opportunity for renal transplant programs to participate in a standardized study that will allow for the collection and documentation of verified outcomes; and,
- Minimal effect upon the distribution of renal organs to blood group A candidates.

The proposed standardized variance will be superimposed on to the allocation algorithm (UNOS policy or local variance) used by the participating OPO. This variance will allow any local unit that wishes to participate to do so simply by meeting the basic requirements for implementing a variance (UNOS Policies 3.1.9 (Alternate Point Assignment, Variances) and 3.4.6 (Application, Review, Dissolution and Modification Process for Alternate Organ

<sup>3</sup> Hume DM, Merrill JP, Miller BF, Thorn GW. Experiences with renal homotransplantation in the human: 1 report of nine cases. *J Clin Invest* 1955; 34: 327

<sup>4</sup> Starzl TE, Marchioro TL, Holes JH, et al. Renal homografts in patients with major donor-recipient blood group incompatibilities. *Surgery* 1964; 55: 195

<sup>5</sup> Brynager H, Rydberg L, Samuelsson B, Blohme I, Lindolm, Sandberg L. Renal transplantation across a blood group barrier: A<sub>2</sub> kidneys to O recipients. *Proc Eur Dial Transplant Assoc Eur Ren Assoc* 1982; 19: 427

<sup>6</sup> Tanabe K, Takahashi K, Sonda K, et al. ABO-incompatible living kidney donor transplantation: results and immunological aspects. *Transplant Proc* 1995; 27(1): 1020

Distribution or Allocation Systems) and then requesting UNOS staff to include their local unit in the study. Individual local units will not be required to obtain UNOS/OPTN Board of Directors approval prior to their participation.

The Minority Affairs Committee, therefore, submits the following Proposal for a Voluntary Kidney Allocation Variance for consideration of public comment:

**RESOLVED, that the proposal from the Minority Affairs Committee, Call for Participation by OPOs in a Local Voluntary Renal Allocation Variance for Transplantation of Blood Group A<sub>2</sub> and A<sub>2</sub>B Cadaveric Kidneys into Blood Group B Waiting List Candidates attached as Exhibit J\* is approved as a standardized national voluntary variance for distribution for public comment, subsequent reconsideration by the Minority Affairs Committee and final recommendation to the UNOS/OPTN Board of Directors following consideration of public comment.**

## **8. Proposed Modifications to UNOS Policy 3.5.2.3 (Mandatory Sharing)**

### **Summary**

The proposed modifications to UNOS Policy 3.5.2.3 (Mandatory Sharing) would eliminate the priority assigned to phenotypic identity for allocating zero antigen mismatched kidneys when there are multiple zero antigen mismatched candidates identified in the match run for a single donor, and require that allocation of these organs be based on waiting time at each level of sequence to which this priority had previously been applied.

### **Background**

Phenotypic identity occurs when both the donor and recipient have the same identified antigens. The priority for phenotypic identity in the mandatory sharing policy was approved by the UNOS/OPTN Board of Directors as a resolution from the Kidney and Pancreas Transplantation Committee at the June 1996 meeting to improve access to zero mismatched kidneys for patients with fewer than six antigens identified. At the time the policy was amended, little was known regarding the impact such a policy would have upon access to transplant for minority candidates. It was suggested, however, that the amended policy should be monitored to determine if it resulted in a detrimental effect. The Minority Affairs Committee has raised questions as to the survival benefit of phenotypic identical recipients over other zero mismatched recipients, and whether this preference further disadvantages minorities in reducing access to zero antigen matched cadaveric kidney transplants.

At the September 7-8, 2000, meeting, the Committee reviewed the result of a multivariate Cox regression analysis of 33,138 cadaveric kidney transplants between 3/6/95 and 6/30/99. The Cox regression analysis was used to allow a review of long-term graft outcome by different human leukocyte antigen (HLA) mismatch levels (i.e., phenotypic identical, other zero mismatch, and 1-6 mismatches) after adjusting for various donor, recipient and transplant risk factors. In this analysis, six-antigen matched recipients are combined with phenotypic identical recipients because every six-antigen matched recipient is also a phenotypic identical recipient. The result of the Cox regression analysis was summarized in terms of risk ratio of each HLA mismatch level as compared to the baseline HLA mismatch level (i.e., other zero mismatch level), as shown in Exhibit K\*. A risk ratio of greater than 1 suggested a higher risk of graft failure, while a risk ratio of less than 1 suggested a decreased risk of graft failure. The table in Exhibit K\* demonstrates no significant differences in long-term graft survival between phenotypic identical matched and other zero antigen mismatched recipients.

Since the phenotypic identity preference is intended to increase access for candidates with fewer than six antigens identified at the A, B and DR loci to zero mismatched kidney transplants, an analysis was also carried out to examine the distribution of HLA blanks in different candidate ethnic groups. Tables 1, 2 and 3 (Exhibit L\*) show, for over 100,000 registrations added to the OPTN/UNOS cadaveric kidney waiting list between 3/6/95 and 6/30/00, the number of blank antigens at the A, B, and DR loci, respectively, for each candidate ethnic group. Registrations with two blank antigens at each of the A, B, and DR loci were excluded. The following table summarizes the frequency of HLA blanks at the three loci by candidate ethnic group.

Candidate Ethnicity	A Locus	B Locus	DR Locus
White	15.13%	8.84%	15.09%
Black	11.71%	8.45%	11.97%
Hispanic	14.15%	8.71%	15.04%
Asian	23.47%	10.42%	18.02%

In general the data show that blank antigens occur less frequently in Black candidates, and most frequently in Asian candidates. Whites and Hispanics have a similar proportion of HLA blanks with each other and intermediate between Blacks and Asians. The relative low incidence of blank antigens in Blacks suggests that Black candidates would be less likely to receive a phenotypic identical matched kidney.

A review of UNOS Kidney Allocation Model<sup>7</sup> (UKAM<sup>sm</sup>) outputs comparing simulations of the current kidney allocation policy (shown as Policy 10 in Exhibit M\*) with an alternative policy (shown as Policy 14 in Exhibit M\*) that eliminates the preference for phenotypic identity for allocating zero antigen mismatched kidneys when there are multiple matches demonstrated very little effects in terms of the number and percent of zero mismatched transplants and percent transplanted at one year after listing for any ethnic group, and overall one- and three-year graft survival (Exhibit M\*). Each policy was modeled for two different time periods, 1999 – 2002, and 1999 – 2004. In each case, results for the first year of the simulation (1999) were cleared, providing three year outputs in the first set of results, and five year outputs in the second set of results.

All of the data reviewed by this Committee indicated that African Americans would be allocated fewer zero mismatched kidneys when preference is given to phenotypic identity, and eliminating this preference would not affect overall long-term graft survival. Elimination of this preference would simplify the mandatory shared allocation sequence and avoid concerns regarding possible disproportionate benefit for African American candidates based upon policy. This proposal has been reviewed by the Histocompatibility Committee and the Kidney and Pancreas Combined Subcommittee on Issues of Equity and HLA Mismatch, both of which support the Minority Affairs Committee’s recommendation.

### Policy Proposal

The Minority Affairs Committee, therefore, by unanimous vote, approved the following motion for distribution for public comment, subsequent reconsideration by the Minority Affairs Committee and final recommendation to the Board of Directors following evaluation of public comment:

**RESOLVED, that OPTN Policy 3.5.2.3 (Mandatory Sharing) shall be amended to eliminate the priority given to phenotypic identical candidates over other zero mismatched candidates when multiple zero antigen mismatches are found for a single donor, and that allocation of that organ shall be based on waiting time at each level of sequence to which this priority has been applied. These modifications are submitted for distribution of public comment, subsequent reconsideration by the Minority Affairs Committee and final recommendation to the Board of Directors following evaluation of public comment.**

**Mandatory Sharing. With the exception of cadaveric kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.2.4, if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the**

<sup>7</sup> UKAM<sup>sm</sup> is a detailed computer simulation of the kidney allocation process in the United States, developed under the oversight of the UNOS Kidney Allocation Modeling Oversight Committee. See, Taranto, S.E., Harper, A.M., Edwards, E.B., Rosendale, J.D., McBride, M.A., Daily, O.P., Murphy, D., Poos, B., Reust, J., Schmeiser, B., 2000. Developing a National Allocation Model for Cadaveric Kidneys. In *Proceedings of the 2000 Winter Simulation Conference*, ed. J.A. Joines, R.R. Barton, K. Kang, and P.A. Fishwick, 1971-1977.

patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.2.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient 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 patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.9.3) four additional points will be added to all patients for whom there is a zero antigen mismatch and whose PRA is 80% or higher regardless of preliminary crossmatch results. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

**3.5.2.3.1 First to identical blood type zero antigen mismatched patients in descending point sequence as follows:**

- ~~i~~ local patients ~~when there is phenotypic identity between the donor and patient;~~ then to
- ~~ii~~ other local patients; then to
- ~~iii~~ 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4, ~~when there is phenotypic identity between the donor and patient;~~ then to
- ~~iv~~ other 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4;; then to
- ~~iiiv~~ 80% or higher PRA patients on the regional waiting list ~~when there is phenotypic identity between the donor and patient;~~ then to
- ~~vi~~ other 80% or higher PRA patients on the regional waiting list; then to
- ~~ivvii~~ 80% or higher PRA patients on the national waiting list ~~when there is phenotypic identity between the donor and patient;~~ then to
- ~~viii~~ other 80% or higher PRA patients on the national waiting list; then to
- ~~vix~~ less than 80% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4, ~~when there is phenotypic identity between the donor and patient;~~ then to
- ~~x~~ other less than 80% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4; then to
- ~~vixi~~ less than 80% PRA patients on the regional waiting list, except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt), ~~when there is phenotypic identity between the donor and patient;~~ then to
- ~~xii~~ other less than 80% PRA patients on the regional waiting list except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term”); then to~~

- ~~viiixiii~~ less than 80% PRA patients on the national waiting list, except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt), when there is phenotypic identity between the donor and patient; then to
- xiv — ~~other less than 80% PRA patients on the national waiting list, except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt);~~

### 3.5.2.3.2

Next to compatible blood type zero antigen mismatched patients in descending point sequence as follows:

- i ~~local patients when there is phenotypic identity between the donor and patient; then to~~
- ii — ~~other local patients; then to~~
- iiiii ~~80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4, when there is phenotypic identity between the donor and patient; then to~~
- iv — ~~other 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4; then to~~
- iiiv ~~80% or higher PRA patients on the regional waiting list when there is phenotypic identity between the donor and patient; then to~~
- vi — ~~other 80% or higher PRA patients on the regional waiting list; then to~~
- ivvii ~~80% or higher PRA patients on the national waiting list when there is phenotypic identity between the donor and patient; then to~~
- viii — ~~other 80% or higher PRA patients on the national waiting list; then to~~
- vix ~~less than 80% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4, when there is phenotypic identity between the donor and patient; then to~~
- x — ~~other less than 80% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.4; then to~~
- vixi ~~less than 80% PRA patients on the regional waiting list, except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt), when there is phenotypic identity between the donor and patient; then to
- xii ~~other less than 80% PRA patients on the regional waiting list, except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt); then to~~
  - viiixiii less than 80% PRA patients on the national waiting list, except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt), when there is phenotypic identity between the donor and patient; then to.
  - xiv ~~other less than 80% PRA patients on the national waiting list except for patients 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 3.5.4.2 (Kidney Payback Debt Limit) for definitions of “short-term” and “long-term” debt); then to~~
  - viiiixv less than 80% PRA patients 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 3.5.4.2 (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.

\* The exhibits referenced in this document are not available electronically. Please contact the Public Comment Coordinator at (804) 327-6760 or via electronic mail ([publiccomment@unos.org](mailto:publiccomment@unos.org)) if you are interested in receiving copies.