This document contains six proposals being offered for public comment. These proposals were developed by OPTN/UNOS committees. When the public comment period ends on December 14, 2012, each sponsoring committee will review the feedback they receive and consider modifications to the original proposals. The OPTN/UNOS Board of Directors may then review and vote on these proposals at its meeting on June 24-25, 2013.

We welcome your feedback on these proposals and other aspects of the public comment process as we continue to improve the way that we communicate with the community.

Please note that all exhibits and appendices to these proposals can be found on the OPTN website via the link below.

Please click on the following link to provide your comments on these proposals:

http://optn.transplant.hrsa.gov/policiesAndBylaws/publicComment/proposals.asp

You may also send general feedback to publiccomment@unos.org

Please submit all comments no later than December 14, 2012. For general questions about the proposals, please contact your Regional Administrator at (804) 782-4800.

Thank you in advance for your careful review and feedback on these proposals.
UNOS and the OPTN: Getting Involved in the Public Comment Process

Under contract with the U.S. Department of Health and Human Services’ Health Services and Resources Administration (HRSA), the United Network for Organ Sharing (UNOS) coordinates the nation’s organ transplant system, providing vital services to meet the needs of men, women and children awaiting lifesaving organ transplants. UNOS unites transplant professionals and organ procurement specialists throughout the nation to match transplant candidates with the organs they need. This nationwide system is called the Organ Procurement and Transplantation Network (OPTN).

The field of organ transplantation depends on the cooperation of many people and organizations, and it is vital to ensure the opinions of all interested parties are heard and addressed. Therefore, the OPTN strives to achieve consensus in the development of policies that determine how organs are allocated throughout the nation.

Committees within the OPTN review transplant data and issues and periodically may draft a new or revised policy to address a particular issue. Before going to the OPTN/UNOS Board of Directors for a vote, UNOS publishes all substantial policy proposals for public comment by other committees, OPTN/UNOS regions and interested persons or organizations. The sponsoring committee will consider all comments received before it makes a final recommendation to the board. The board then considers policy proposals in light of the input received.

Final decisions about policy proposals are published on the OPTN and UNOS web sites. A policy notice detailing all board-approved policy changes is sent to OPTN/UNOS members and other interested parties approximately 30 days after the board meeting. This notice includes all implementation dates that are available at the time of publication.

Input from transplant candidates – the people most affected by new or revised policy – is an important part of the public comment process. The OPTN strongly encourages all interested individuals – especially transplant candidates – to express their views on policy proposals by getting involved in the public comment process.

You can view proposals that go out for public comment several ways. You can visit the OPTN and UNOS web sites directly at www.optn.org or www.unos.org, or you can send an e-mail to publiccomment@unos.org and sign up to receive e-mail notification of future documents. If you are unable to access the Internet, you can receive a paper copy of the document by calling or faxing a request to the UNOS public comment coordinator. You may also submit a written request to UNOS.

For more information, please contact:

Public Comment Coordinator
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218
Phone: (804)782-4877
FAX (804) 782-4896
E-mail: publiccomment@unos.org
Specific questions about policy proposals can be answered by the UNOS Regional Administrator for your area. Please consult the listing below to determine your regional contact person.

**Shannon Edwards (edwardsf@unos.org)**
Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
Region 4 - Oklahoma, Texas
Region 9 - New York, Western Vermont

**Betsy Gans (gansel@unos.org)**
Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming

**Clifton McClennen (mcclence@unos.org)**
Region 3 - Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

**Chrystal Oley-Graybill (graybioe@unos.org)**
Region 5 - Arizona, California, Nevada, New Mexico, Utah
Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 10 - Indiana, Michigan, Ohio
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I. **Summary of Public Comment Proposals Distributed September 21, 2012**

1. **Proposal to Substantially Revise The National Kidney Allocation System (Kidney Transplantation Committee)**

   This proposal seeks to substantially revise the national kidney allocation system to enhance post-transplant survival benefit, increase utilization of donated kidneys and increase transplant access for biologically disadvantaged candidates. The proposal incorporates new features such as an expanded definition of waiting time, a sliding scale for assigning points to sensitized patients, expanded access for blood type B candidates who can accept kidneys from subtypes of blood type A donors, broader sharing for extremely highly sensitized candidates, longevity matching of some kidneys, and regional sharing for kidneys with the highest risk of discard. The proposed changes are estimated to result in an additional 8,380 life years achieved annually from the current pool of deceased donor kidneys while improving access for sensitized candidates and minority candidates.

2. **Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion (Pancreas Transplantation Committee)**

   The goal of this proposal is to require the accurate and timely reporting of every islet infusion to the OPTN Contractor and to update language in policies and bylaws to reflect current practice for reporting islet infusions and outcomes information. Currently, islet Transplant Programs are not required to report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have implications for patient safety or disease transmission. This proposal:

   1. Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
   2. Removes outdated requirements in the bylaws for submitting islet logs.
   3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed from the waiting list for transplant and immediately re-registered for another infusion.

3. **Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation (Thoracic Organ Transplantation and Membership and Professional Standards Committees (MPSC))**

   The proposed change removes an OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

   A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to
transplant organs for which the transplant hospital has already been approved. Aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. The combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

4. **Proposal to Change the Composition of the OPTN Finance Committee (Executive Committee)**

To improve the efficient management of the OPTN, this proposal recommends changing the composition of the OPTN Finance Committee so that it is consists of members of the OPTN Board of Directors. Currently, the OPTN Finance Committee is a permanent standing committee with regional and at-large appointments, and it reports to the OPTN Board of Directors. For most organizations, financial governance begins with a finance committee that resides at the board level.

5. **Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity (Membership and Professional Standards Committee (MPSC))**

The purpose of this proposal is to better define the notification requirements for periods of functional inactivity. Currently, the Bylaws do not clearly outline the actions a Member must take when it becomes functionally inactive. This Bylaw proposal clarifies the current notification requirements for functional inactivity by including specific requirements for notification of functional inactivity, including waiting list inactivation in UNet™. These modifications also specify what a member must do in terms of notifying patients when a program voluntarily ceases performing a specific type of transplant.

6. **Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee)**

The proposed changes clarify the data collection definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs must classify a death as one of the following: Imminent Neurologic Death (“imminent”), Eligible Death (“eligible”), or neither “eligible” nor “imminent” (“neither”). The OPOs then report the “imminent” and “eligible” deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The changes proposed by the Committee eliminate multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as “eligible” and add a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of “imminent” to restrict it to those deaths that would most likely be classified as “eligible” had brain death been legally declared. This change could allow the combination of “eligible” and “imminent” deaths to mitigate the effect of the variation in brain death laws.
## II. Overview of Policy Proposals and Affected Groups

<table>
<thead>
<tr>
<th>Proposal Number</th>
<th>Policy/Bylaw Change and Sponsoring Committee</th>
<th>Directors of Organ Procurement</th>
<th>Lab Directors/Supervisors</th>
<th>OPO Coordinators</th>
<th>OPO Data Coordinators</th>
<th>OPO Medical Directors</th>
<th>OPO Procurement Coordinators</th>
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<th>Transplant Data Coordinators</th>
<th>Compliance Officers</th>
<th>Transplant Physicians/Surgeons</th>
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<th>Organ Recipient</th>
<th>Organ Donor</th>
<th>Living Donor</th>
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<th>Donor Advocate</th>
<th>General Public</th>
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<td>4</td>
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III. Policy Proposals

At-a-Glance

- **Proposal to Substantially Revise The National Kidney Allocation System**

- **Affected/Proposed Policy:** 3.5 Allocation of Deceased Donor Kidneys

- **Kidney Transplantation Committee**

- This proposal seeks to substantially revise the national kidney allocation system to enhance post-transplant survival benefit, increase utilization of donated kidneys and increase transplant access for biologically disadvantaged candidates. The proposal incorporates new features such as an expanded definition of waiting time, a sliding scale for assigning points to sensitized patients, expanded access for blood type B candidates who can accept kidneys from subtypes of blood type A donors, broader sharing for extremely highly sensitized candidates, longevity matching of some kidneys, and regional sharing for kidneys with the highest risk of discard. The proposed changes are estimated to result in an additional 8,380 life years achieved annually from the current pool of deceased donor kidneys while improving access for sensitized candidates and minority candidates.

- **Affected Groups**
  - Directors of Organ Procurement
  - Lab Directors/Supervisors
  - OPO Executive Directors
  - OPO Medical Directors
  - OPO Coordinators
  - Transplant Administrators
  - Transplant Data Coordinators
  - Transplant Physicians/Surgeons
  - PR/Public Education Staff
  - Transplant Program Directors
  - Transplant Social Workers
  - Organ Candidates
  - Donor Family Members
  - General Public

- **Number of Potential Candidates Affected**
  - As of July 19, 2012, there were 92,696 candidates listed for a kidney or kidney-pancreas transplant. All of these candidates will be affected in some way by the proposed changes.

- **Compliance with OPTN Strategic Goals and Final Rule**
  - This proposal is expected to meet the OPTN Key Goals of increasing access to transplant and improving post-transplant survival for recipients. Additionally, this proposal will reset kidney allocation variances to comply with the requirements set forth in the OPTN Final Rule.
Proposal to Substantially Revise the National Kidney Allocation System

Affected/Proposed Policy: 3.5 Allocation of Deceased Donor Kidneys

Kidney Transplantation Committee

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

This proposal seeks to substantially revise the national kidney allocation system to enhance post-transplant survival benefit, increase utilization of donated kidneys and increase transplant access for biologically disadvantaged candidates. The proposal incorporates new features such as an expanded definition of waiting time, a sliding scale for assigning points to sensitized patients, expanded access for blood type B candidates who can accept kidneys from subtypes of blood type A donors, broader sharing for extremely highly sensitized candidates, longevity matching of some kidneys, and regional sharing for kidneys with the highest risk of discard. The proposed changes are estimated to result in an additional 8,380 life years achieved annually from the current pool of deceased donor kidneys while improving access for sensitized candidates and minority candidates. Additionally, the proposed changes are believed to reduce the discard rate, thereby making more kidneys available for transplantation. Finally, the proposed changes are expected to streamline the kidney allocation system and improve efficiency.

Background and Significance of the Proposal:

These revisions to kidney allocation policy were developed in response to feedback provided by transplant professionals, patients, donor family members, and the general republic regarding organ allocation and limitations of the current kidney allocation system. Such limitations include:

- higher than necessary discard rates of kidneys that could benefit candidates on the waiting list,
- variability in access to transplantation by candidate blood type and geographic location, and
- many kidneys with long potential longevity being allocated to candidates with significantly shorter potential longevity and vice versa. This results in unrealized graft years and unnecessarily high retransplant rates.

The Organ Procurement and Transplantation Network (OPTN) Kidney Transplantation Committee worked with the OPTN and Scientific Registry of Transplant Recipients (SRTR) contractors since 2003 to design a kidney allocation system which addresses the above limitations and meets the following objectives:

- More accurately estimate graft longevity and recipient longevity to maximize the potential survival of every transplanted kidney within biological reason and to provide acceptable levels of access for those on the waiting list.
- Promote post-transplant kidney function for candidates with the longest estimated post-transplant survival and who are likely to require additional transplants due to early age of end stage renal disease (ESRD).
- Minimize loss of potential functioning years of deceased donor kidney grafts through improved matching.
• Improve offer system efficiency and organ utilization through the introduction of a new scale for kidney quality, called the kidney donor profile index (KDPI).
• Make comprehensive data better available to patients and transplant programs to guide them in their treatment choices.
• Reduce differences in transplant access for populations described in the National Organ Transplant Act (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).

The following table lists some of the major events undertaken in the formulation of this proposal.

<table>
<thead>
<tr>
<th>Date</th>
<th>Sentinel Event</th>
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<tbody>
<tr>
<td>2003</td>
<td>OPTN Board of Directors instructs the Kidney Allocation Review Subcommittee (KARS) to conduct a 360 degree review of the current kidney allocation system. This review included a series of public hearings to better understand the limitations of the current system and possible approaches for improvement.</td>
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<td>2004</td>
<td>OPTN Board of Directors instructs KARS to examine the use of net lifetime survival benefit in a revised allocation system.</td>
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<td>2005</td>
<td>KARS merges with the OPTN Kidney Transplantation Committee to begin formal policy development process.</td>
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<tr>
<td>2007</td>
<td>Public Forum held in Dallas, Texas to review the use of life years from transplant (LYFT) in an allocation system.</td>
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<tr>
<td>September 2008</td>
<td>Request for Information (RFI) issued detailing the concepts of life years from transplant (LYFT), kidney donor profile index (KDPI), and changes to the waiting time calculation to include time on dialysis prior to listing.</td>
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<td>January 2009</td>
<td>Public forum held in Saint Louis Missouri to review concepts circulated in September 2008. Participants included representatives from the following organizations:</td>
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<td></td>
<td>● American Association of Kidney Patients</td>
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<tr>
<td></td>
<td>● American Society of Histocompatibility and Immunogenetics</td>
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<td>● American Society of Transplant Surgeons</td>
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<td>● American Society of Transplantation</td>
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<td></td>
<td>● National Association of Transplant Coordinators</td>
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<td></td>
<td>● National Kidney Foundation</td>
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<td>● Renal Support Network</td>
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<td>2009</td>
<td>At the recommendation of forum participants, the Committee considers age matching as a way to address concerns about system complexity.</td>
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<tr>
<td>February 2011</td>
<td>Concept document is released detailing the use of estimated post transplant survival (EPTS), age matching within 15 years of donor and recipient, and kidney donor profile index (KDPI).</td>
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<tr>
<td>August 2011</td>
<td>Committee receives feedback suggesting that age matching does not meet the requirements of the 1979 Age Discrimination Act since it uses age as an arbitrary determinant in allocation.</td>
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<tr>
<td>2011-2012</td>
<td>Committee considers alternatives to age matching.</td>
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<tr>
<td>September 2012</td>
<td>Committee issues a proposal for public comment.</td>
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</table>
As of July 19, 2012, 92,696 individuals were listed for kidney transplant. The demand for kidney transplant has steadily increased since the OPTN began keeping records. However, the number of kidneys available from deceased donors has not kept pace with the increasing demand. The demand is projected to continue to grow given the increases in the number of Americans with end stage renal disease (ESRD) and chronic kidney disease (CKD) (Figure 1).

![Figure 1: End stage renal disease (ESRD) incident and prevalent patient counts, by modality]

In a perfect scenario, all who need a kidney transplant would receive one without delay. However, the shortage of deceased donor organs means that most candidates for kidney transplantation have to wait, oftentimes for years before receiving a transplant. Some transplant candidates do not survive long enough to receive a kidney from a deceased donor and die while on the waiting list. Other candidates are fortunate to receive a kidney from a living donor. While the number of living donor transplants has increased over time, even with these additional kidneys, there is not enough supply to provide a transplant to all who need one.

Organ allocation is the process the OPTN uses to determine which transplant candidates are offered which organs. Each organ allocation system attempts to achieve different goals. For example, livers are allocated based on a candidate’s chance of dying while waiting for a transplant. Those candidates at highest risk are transplanted ahead of candidates at lower risk. Lungs are allocated based on the candidate’s chance of dying while waiting for a transplant and also on the chance of dying during the first year following transplant. In this way, the liver and lung allocation systems both attempt to minimize death on the waiting list. The lung allocation system is designed also to maximize survival in the first year after transplant. In contrast, kidneys are currently allocated based primarily on how long a candidate has been on the waiting list.

Waiting time’s status as the primary determinant in the kidney allocation system has evolved gradually. The kidney allocation system was initially designed so that candidates who were close biological matches with a donated kidney received more priority than candidates who were not as close of a biological match. In the past, closer biological matching was necessary for acceptable patient and graft survival. With improvement in anti-rejection medications, the priority for tissue typing has been

decreased greatly over the last several decades. While the current design of giving most of the priority based on waiting time may be perceived as “fair”, it does not strive to minimize death on the waiting list nor maximize survival following transplant. It does not recognize that all candidates do not have the same ability to survive the wait. It does not attempt to match the characteristics of a donor’s kidney to the candidate’s characteristics to promote a long and healthy survival post-transplant. The system can be designed to achieve more in the way of patient health and longevity, as well as more efficient utilization of a limited resource than it currently does.

With the belief that the system can be improved, the Kidney Transplantation Committee, under direction from the OPTN Board of Directors, set out to design a new kidney allocation system. Over the past nine years, this process has involved hundreds of individuals including transplant professionals, transplant recipients, transplant candidates, donor family members, living donors, and members of the general public.

**Brief Description of Proposed System:**

Currently, the kidney allocation sequence has four distinct pathways based on the characteristics of the kidney. Kidneys from donors younger than 35 are allocated preferentially to pediatric candidates. Kidneys from expanded criteria donors (ECD) are allocated to candidates who consent to receiving these organs. Kidneys from standard criteria donors (SCD) are allocated to all candidates on the waiting list. Kidneys from donation after cardiac death (DCD) donors are allocated according to a sequence that speeds placement by focusing on local distribution.

Similarly, there are four distinct pathways for kidney allocation within the proposed system. Unlike the current system which uses different criteria for determining the pathways (ECD status, DCD status, donor age), the proposed system uses the kidney donor profile index (KDPI). The diagram below demonstrates the four different pathways based on KDPI. For example, if a kidney becomes available with a KDPI score greater than 20% but less than 35%, then the kidney would follow allocation sequence B. For reference, kidneys with higher estimated quality have lower KDPI scores.
The following table provides a summary of the allocation categories for each of the sequences. Detailed allocation sequences may be found in section 3.5.6 of the proposed policy language.

<table>
<thead>
<tr>
<th>Sequence A</th>
<th>Sequence B</th>
<th>Sequence C</th>
<th>Sequence D</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI &lt;=20%</td>
<td>KDPI &gt;20% but &lt;35%</td>
<td>KDPI &gt;=35% but &lt;=85%</td>
<td>KDPI&gt;85%</td>
</tr>
<tr>
<td>Local CPRA 100</td>
<td>Local CPRA 100</td>
<td>Local CPRA 100</td>
<td>Local CPRA 100</td>
</tr>
<tr>
<td>Regional CPRA 100</td>
<td>Regional CPRA 100</td>
<td>Regional CPRA 100</td>
<td>Regional CPRA 100</td>
</tr>
<tr>
<td>National CPRA 100</td>
<td>National CPRA 100</td>
<td>National CPRA 100</td>
<td>National CPRA 100</td>
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<tr>
<td>Local CPRA 99</td>
<td>Local CPRA 99</td>
<td>Local CPRA 99</td>
<td>Local CPRA 99</td>
</tr>
<tr>
<td>Regional CPRA 99</td>
<td>Regional CPRA 99</td>
<td>Regional CPRA 99</td>
<td>Regional CPRA 99</td>
</tr>
<tr>
<td>Local CPRA 98</td>
<td>Local CPRA 98</td>
<td>Local CPRA 98</td>
<td>Local CPRA 98</td>
</tr>
<tr>
<td>Zero mismatch (top 20% EPTS)</td>
<td>Zero mismatch</td>
<td>Zero mismatch</td>
<td>Zero mismatch</td>
</tr>
<tr>
<td>Prior living organ donor</td>
<td>Prior living organ donor</td>
<td>Prior living organ donor</td>
<td>Prior living organ donor</td>
</tr>
<tr>
<td>Local pediatrics</td>
<td>Local pediatrics</td>
<td>Local pediatrics</td>
<td>Local</td>
</tr>
<tr>
<td>Local top 20% EPTS</td>
<td>Local adults</td>
<td>Regional pediatrics</td>
<td>Regional</td>
</tr>
<tr>
<td>Zero mismatch (all)</td>
<td>Regional adults</td>
<td>Regional (top 20%)</td>
<td>Regional (all)</td>
</tr>
<tr>
<td>Local (all)</td>
<td>National pediatrics</td>
<td>National (top 20%)</td>
<td>National (all)</td>
</tr>
<tr>
<td>Regional pediatrics</td>
<td>National pediatrics</td>
<td>National (all)</td>
<td>*all categories in Sequence D are limited to adult candidates</td>
</tr>
<tr>
<td>Regional (all)</td>
<td>National pediatrics</td>
<td>National (all)</td>
<td></td>
</tr>
<tr>
<td>National pediatrics</td>
<td>National pediatrics</td>
<td>National (all)</td>
<td></td>
</tr>
<tr>
<td>National (top 20%)</td>
<td>National pediatrics</td>
<td>National (all)</td>
<td></td>
</tr>
<tr>
<td>National (all)</td>
<td>National pediatrics</td>
<td>National (all)</td>
<td></td>
</tr>
</tbody>
</table>

Within each category, candidates are rank-ordered according to points. Briefly, the proposed point system is as follows:

- 1 point per year (awarded as 1/365 points per day) for qualified time spent waiting
- 0-202 points based on degree of sensitization (as determined by CPRA)
- 0-2 points for degree of HLA-DR matching
- 4 points for prior living organ donors
- 1 point for pediatric candidates if donor is less than 35 years old
- 4 points for pediatric candidates (aged 0-10 at time of match) when offered a zero antigen mismatch
- 3 points for pediatric candidates (aged 11-17 at time of match) when offered a zero antigen mismatch

Once candidates are rank-ordered within the appropriate categories of an allocation sequence, the organ procurement organization (OPO) can begin to make offers. These offers are made for specific candidates in the order they appear on the OPTN Match Run. Just as they are now, OPOs would be required to follow the Match Run and administrative policies when placing kidneys under the proposed system.

**Alternatives Considered:**

The Committee evaluated several different approaches to kidney allocation during this process. Over 50 simulation runs were conducted with the majority falling into the following themes or combinations of themes:
• *Life years from transplant (LYFT)*: All candidates would be ranked according to their likelihood of realizing the full survival potential of a given organ. Feedback on this approach indicated that it was too complex as candidate priority could fluctuate greatly from one offer to the next. Transplant programs expressed concern that they would not be able to adequately maintain workups for all candidates on their waiting lists to accommodate such a system.

• *Age matching*: Candidates within 15 years (older/younger) of the donor would be prioritized ahead of candidates outside of the age band. This approach was found to be problematic because it used candidate age as a hard demarcation in the allocation system. After consultation with legal experts, the Committee decided not to pursue this approach as it may be perceived as age discrimination.

• *Matching of candidates and donors within quality bands*: The waiting list would be divided into five categories based on life years from transplant (LYFT) scores. Kidneys would also be divided into five categories based on kidney donor profile index (KDPI) scores. Kidneys would be allocated first to candidates in the same category before being allocated outside of the category. The Committee found that this approach resulted in substantial differences in waiting times for candidates in different categories.

Ultimately, the Committee found that the current system could be modified slightly to provide better outcomes for 80% of candidates on the list. For the remaining 20% of candidates, the Committee also recommends more substantial changes. The Committee decided to recommend that the 20% of candidates with the longest estimated post transplant survival (EPTS) have priority for the top 20% of kidneys in terms of estimated donor quality, as measured by the kidney donor profile index (KDPI). When coupled with refinements in the way candidates are rank-ordered, the Committee found that longevity matching (Top 20% of kidneys prioritized to Top 20% of candidates) is projected to achieve significantly more life years and graft years than the current kidney allocation system, without substantially diminishing access to any one group of candidates.

Table 2 outlines the current and proposed systems. Additional details are provided in later sections.

<table>
<thead>
<tr>
<th>Brief Overview of Proposed Changes to the Waiting Time Calculation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current</strong></td>
<td><strong>Proposed</strong></td>
</tr>
<tr>
<td>Adult candidates begin accruing waiting time when listed once on dialysis or with a glomerular filtration rate [GFR] of less than or equal to 20 ml/min.</td>
<td>Adult candidates would begin to accrue waiting time when listed once on dialysis or with a GFR less than or equal to 20 ml/min. Candidates would also receive a credit for time spent on dialysis prior to listing.</td>
</tr>
<tr>
<td>Pediatric candidates begin to accrue time immediately upon listing</td>
<td>Pediatric candidates will still immediately begin to accrue time upon listing or will receive credit for prior dialysis if applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Brief Overview of Proposed Changes to Priority for Sensitized Candidates</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current</strong></td>
<td><strong>Proposed</strong></td>
</tr>
<tr>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>
Candidates with a calculated panel reactive antibody [CPRA] score over 80% receive 4 points.

Local candidates with extremely high CPRA (80%) and high total scores are categorized ahead of local candidates with lower scores.

Candidates with CPRA scores of 20% or above would receive points based on a sliding scale commensurate with CPRA.

Local, regional and national candidates with CPRA =100%, regional and national candidates with CPRA =99%, and local candidates with CPRA =98% will appear before candidates with zero-antigen mismatches.

<table>
<thead>
<tr>
<th>Brief Overview of Proposed Changes to Blood Type Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
</tr>
<tr>
<td>Kidneys are allocated to candidates who are blood type identical to the donor when the donor has blood type O or blood type B.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Brief Overview of Proposed Changes to Candidate Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
</tr>
<tr>
<td>Adult candidates are not prioritized based on estimated patient survival.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Brief Overview of Proposed Change to Pediatric Kidney Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
</tr>
<tr>
<td>Pediatric candidates receive additional priority for kidneys from donors age of 35 or younger.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Brief Overview of Proposed Change to Kidney Classifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
</tr>
<tr>
<td>Kidneys are classified as either coming from standard criteria donors (SCD) or expanded criteria donors (ECD) based on donor age, history of hypertension, creatinine, and cerebrovascular accident as cause of death.</td>
</tr>
</tbody>
</table>

| Brief Overview of Proposed Change to Kidney Payback Policy |
When a kidney is transplanted outside of the procuring donation service area (DSA), the receiving DSA is required to pay back a kidney. Kidneys are most likely to be shared as zero antigen mismatches, or as kidney/extra-renal transplants.

<table>
<thead>
<tr>
<th>Current</th>
<th>Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paying back a kidney would no longer be required or allowed.</td>
<td></td>
</tr>
</tbody>
</table>

### Brief Overview of Changes to Kidney Variances

<table>
<thead>
<tr>
<th>Current</th>
<th>Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are currently several regional and local variances to national kidney allocation policy. These include variances to geographic distribution units, allocation points, and allocation categories.</td>
<td></td>
</tr>
<tr>
<td>The Committee-sponsored alternative allocation systems for $A_2/A_2B$ kidneys for $B$ recipients and the system for allowing dialysis time to commence from the start of dialysis will be incorporated into national policy. All other variances will be eliminated at the time a new national kidney allocation system is implemented.</td>
<td></td>
</tr>
</tbody>
</table>

### a. Proposed Changes to Kidney Classifications

In the current kidney allocation system, kidneys are classified as either coming from a standard criteria donor (SCD) or an expanded criteria donor (ECD). These classifications result in different allocation sequences and transplant programs are required to obtain additional consent from candidates who elect to receive ECD kidneys. The ECD classification was implemented in 2002 and is based on combinations of the following criteria: death from cerebrovascular accident, hypertension, creatinine greater than 1.5 mg/dL, and donor age. Kidneys from donors over age 60, or kidneys from donors between 50 and 59 with two of the following (hypertension, creatinine > 1.5 mg/dL, death from cerebral vascular accident) are classified as ECD.

Unfortunately, these two classifications have resulted in the labeling of kidneys as either “good” or “bad”. In analyses of the KDRI, some ECD kidneys have been found to have better function than some SCD kidneys, as represented by the overlapping histograms in Figure 2.

**Figure 2: Overlapping kidney donor risk index (DRI) of SCD and ECD kidneys**

![Histogram comparing SCD and ECD kidney donor risk index categories](image-url)
The Committee proposes that the dichotomous labeling system be replaced with a continuous scale, the kidney donor profile index (KDPI). The KDPI is a numerical measure that combines ten dimensions of information about a donor, including clinical parameters and demographics, to express the quality of the donor kidneys relative to other donors. The KDPI is derived by first calculating the Kidney Donor Risk Index (KDRI), using strictly donor factors, for a deceased donor.\(^2\)

A donor with a KDPI of 90%, for example, has an estimated risk of graft failure (as per the KDRI) greater than 90% of donors in the chosen reference population. In this way, the KDPI is simply a mapping of the KDRI from a relative risk scale to a cumulative percentage scale. The reference population of donors is all donors in the U.S. from whom a kidney was recovered during the prior year. Lower KDPI values are associated with increased donor quality; higher KDPI values are associated with lower donor quality.

The following donor factors are used to calculate KDPI:

- Age
- Height
- Weight
- Ethnicity
- History of Hypertension
- History of Diabetes
- Cause of Death
- Serum Creatinine
- Hepatitis C Virus (HCV) Status
- Donation after Circulatory Death (DCD) Status

The association between these donor factors and graft survival was determined by estimating a multivariable Cox proportional hazards regression model using graft outcomes from nearly 70,000 adult, solitary, first-time deceased donor kidney recipients in the U.S. from 1995-2005. The estimated coefficients derived from this model are shown in Table 3.

<table>
<thead>
<tr>
<th>Donor Characteristic</th>
<th>Applies to:</th>
<th>KDRI Coefficient (“Beta”)</th>
<th>KDRI “XBeta” Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (integer years)</td>
<td>All donors</td>
<td>0.0128</td>
<td>0.0128*(age-40)</td>
</tr>
<tr>
<td></td>
<td>Donors with age &lt; 18</td>
<td>-0.0194</td>
<td>-0.0194*(age-18)</td>
</tr>
<tr>
<td></td>
<td>Donors with age &gt; 50</td>
<td>0.0107</td>
<td>0.0107*(age-50)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>All donors</td>
<td>-0.0464</td>
<td>-0.0464*(hgt-170)/10</td>
</tr>
</tbody>
</table>

KDPI provides more information about donated kidneys than the current SCD/ECD classifications. In March 2012, the KDPI value began being displayed in DonorNet®. The purpose of this display is to help inform clinicians when making offer acceptance decisions, as well as to provide clinicians practical experience with the calculation before any possible use in an allocation system. Whereas the ECD classification indicates that a kidney has a risk of graft failure estimated to be 1.7 times greater than the average SCD kidney, the KDPI provides a continuous scale that is highly correlated with graft and patient survival (Figure 3).

<table>
<thead>
<tr>
<th></th>
<th>Donors with weight &lt; 80kg</th>
<th>-0.0199</th>
<th>-0.0199*(wgt-80)/5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>African American donors</td>
<td>0.1790</td>
<td>0.1790</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>Hypertensive donors</td>
<td>0.1260</td>
<td>0.1260</td>
</tr>
<tr>
<td>History of Diabetes</td>
<td>Diabetic donors</td>
<td>0.1300</td>
<td>0.1300</td>
</tr>
<tr>
<td>Cause of Death</td>
<td>Donors with cerebrovascular accident as cause of death</td>
<td>0.0881</td>
<td>0.0881</td>
</tr>
<tr>
<td>Serum Creatinine</td>
<td>All donors</td>
<td>0.2200</td>
<td>0.2200*(creat-1)</td>
</tr>
<tr>
<td></td>
<td>Donors with creatinine &gt; 1.5 mg/dL</td>
<td>-0.2090</td>
<td>-0.2090*(creat-1.5)</td>
</tr>
<tr>
<td>HCV status</td>
<td>HCV positive donors</td>
<td>0.2400</td>
<td>0.2400</td>
</tr>
<tr>
<td>DCD Status</td>
<td>DCD donors</td>
<td>0.1330</td>
<td>0.1330</td>
</tr>
</tbody>
</table>

Figure 3: Estimated Graft Survival Rates by KDPI

The Committee recognizes the need for efficient placement of kidneys with higher KDPI scores which have lower expected longevity and are often less likely to be accepted for transplant. Therefore, it recommends allocating kidneys with KDPI scores greater than or equal to 85% to a combined local and
regional list of candidates, and according to a simpler algorithm based only on waiting time. Unlike the current ECD/SCD classifications, an expedited system for higher risk kidneys based on KDPI can be modified over time. In the future, the line of demarcation could be moved to 75% or 90% to include more or fewer kidneys in this pathway of the allocation algorithm in response to changing waiting list dynamics.

b. Proposed Addition to Candidate Classifications; Longevity Matching
In the current kidney allocation system, candidates are classified according to pediatric or adult, sensitized (CPRA >=80%, or CPRA between 21% and 79%) or unsensitized, and blood type. Unlike the liver allocation system or the lung allocation system, the current kidney allocation system does not have a candidate classification based risk of death while on the waiting list or estimated post-transplant survival. Incorporating a metric like estimated post-transplant survival would allow for better matching of candidates and donated grafts so that individuals with very long estimated post transplant survival do not receive kidneys with very short survival (necessitating a second or third transplant from an already limited donor pool) and vice versa.

The Committee investigated several approaches to matching graft and patient survival. Among these, life years from transplant, or LYFT, was debated in two public forums. The feedback received on LYFT was that it was made up of too many variables and that an allocation system which attempted to match each kidney and patient was too complicated and unpredictable to be feasible. Based on this feedback, the Committee revised its approach and decided to use a simplified, four-variable metric, (estimated post-transplant survival (EPTS)), instead of a “net-benefit” approach like LYFT, which also takes into account a candidate’s estimated survival on dialysis. The Committee further decided to limit the use of EPTS in an allocation system to only 20% of donated kidneys. If longevity matching proves to be a successful approach for kidney allocation, future policy iterations could expand the number of kidneys and candidates which participate.

EPTS is based on the following four factors: candidate age, length of time on dialysis, prior transplant (any organ) and diabetes status. These factors were selected for the metric because they are available in the OPTN database, are clinically relevant, statistically significant, and are objective. While other factors, such as cardiovascular health, affect survival, an objective metric is not currently available in the OPTN database. As the field of transplantation advances, study of additional factors could lead to their incorporation into the dataset and ultimately into allocation policy. The formula for EPTS was derived using a Cox proportional hazards model to estimate survival of kidney transplant recipients and is shown below. Higher EPTS scores are associated with lower expected patient survival.

\[
\text{EPTS SCORE} = \\
0.047 \times \text{MAX(Age} - 25, 0) + \\
-0.015 \times \text{Diabetes} \times \text{MAX(Age} - 25, 0) + \\
0.398 \times \text{Prior Organ Transplant} + \\
-0.237 \times \text{Diabetes} \times \text{Prior Organ Transplant} + \\
0.315 \times \text{log(Years on Dialysis} + 1) + \\
-0.099 \times \text{Diabetes} \times \text{log(Years on Dialysis} + 1) + \\
0.130 \times \text{(Years on Dialysis} = 0) + \\
-0.348 \times \text{Diabetes} \times \text{(Years on Dialysis} = 0) + \\
1.262 \times \text{Diabetes}
\]
The Committee determined that introducing longevity matching for all candidates at this time is not a viable policy option. In the proposed system, only 20% of candidates who have the longest EPTS would receive offers for kidneys from donors with KDPI scores of 20% or less before other candidates at the local, regional, and national levels of distribution. Kidneys from donors with KDPI scores greater than 20% would be allocated to all candidates based on allocation points.

The Committee examined the distribution of KDPI and EPTS across donation service areas (DSAs). The majority of DSAs had between 15% and 25% of donors with a KDPI score of 20% or less (Figure 4). The majority of DSAs also had between 15% and 25% of candidates with an EPTS score of 20% or less (Figure 5). The relationship between the percent of donors and candidates in the top 20% of KDPI and EPTS, respectively, is shown in Figure 6 and Figure 7. These figures show that the majority of DSAs have donor and candidate populations with KDPI and EPTS scores respectively that both fall within +/-5% of the 20% threshold. The percentage of donors within the 20% KDPI threshold appears to be only weakly correlated with the percentage of candidates within the 20% EPTS threshold.
During this process, questions have arisen regarding an allocation system in which waiting time, though still a key factor, is not the single most dominant factor driving the prioritization of candidates. Many transplant programs today rely on the “predictability” of the current allocation system and, due to the
size of their waiting list, may only maintain current workups on candidates who are most likely to receive a transplant within the next year, for example. Feedback from the transplant community indicated that some kidney programs would have difficulty maintaining workups in candidates who fluctuated into and out of the top 20% category. However, due to the nature of the factors used in the calculation, expected post transplant survival tends to decline over time and only rarely will a candidate’s EPTS score improve with time. Age, time on dialysis, and prior transplant are all negative factors in the score. The only opportunity for improvement would be reversal of diabetes, but even that would not lead to a substantial improvement. Furthermore, individual candidate EPTS scores are proposed to be updated quarterly, as opposed to daily, further reducing EPTS fluctuations. Consequently, the Committee does not expect candidates to frequently fluctuate into and out of the top 20% in terms of EPTS.

The Committee considered the predictive accuracy of the EPTS calculation, or how well it can rank order candidates according to estimated longevity. The index of concordance or c-statistic for the EPTS calculation is estimated to be 0.693 (SE=0.002). For comparison, the c-statistic for another allocation model, the Model for End Stage Liver Disease (MELD), is estimated to be 0.867. The predictive ability for the EPTS calculation is not as high as for MELD; however, EPTS is not being considered as a tool for rank-ordering candidates in the same way as MELD does. Whereas liver transplant candidates are rank-ordered according to their MELD scores, the kidney allocation system would only use EPTS to categorize candidates into two broad groups: the top 20% longevity group, and the bottom 80% group. Candidates would then be rank-ordered within these groups according to allocation points.

Though a c-statistic of nearly 0.70 is considered reasonably good for a predictive model, the EPTS score does not always accurately predict which of two clinically similar candidates will actually survive longer. This difficulty is caused by sources of variability not included in the EPTS model, such as donor characteristics, recipient compliance with treatment, transplant program effects, and other measured as well as unmeasured factors. Even in a “full” model including all measured and available factors predictive of kidney transplant outcomes, the c-statistic for distinguishing recipient longevity tops out at around 0.71. This suggests that the simplified, 4-factor EPTS model has not lost significant predictive power compared to the maximum predictive capability possible given the currently available data. Though EPTS may have some difficulty distinguishing between clinically similar candidates, the expected longevity of recipients at opposite ends of the EPTS spectrum is very different.

c. Proposed Changes to the Waiting Time Calculation

As waiting time remains a core component of the proposed allocation system, this proposal seeks to refine the definition of waiting time to include the time that a patient with ESRD spent on dialysis prior to being listed for transplant. For candidates who have received a prior kidney transplant, only dialysis time since the most recent transplant applies. This proposed change is expected to increase the transplant rate for underserved (often ethnic minority) populations who may not receive adequate information to pursue transplant at the time of dialysis initiation and thus may be added to the waitlist long after their ESRD diagnosis. Current policy permits waiting time to start at registration if a candidate is either on dialysis or with a GFR<20 ml/min.

In November 2004, the OPTN Board of Directors approved a voluntary pilot study regarding alternative kidney waiting time calculations. The study assessed the impact on kidney allocation from permitting kidney waiting time accrual to commence from the time of initiation of chronic maintenance dialysis, even if this time pre-dated the date of listing. The study did not change current policy allowing waiting time (1) for adult candidates who have not yet initiated chronic maintenance dialysis to accrue upon
attaining a minimum creatinine clearance level or calculated GFR, with no time accrued based upon these criteria prior to the date of the candidate’s listing, and (2) for pediatric candidates who have not yet initiated chronic maintenance dialysis to accrue upon date of wait listing. The intent of the study was to test the effect of a change in the definition of waiting time on access to transplantation within participating DSAs. Since implementation in 2006, three OPOs have elected to participate in the study: OneLegacy in California, Iowa Donor Network, and Gift of Life Michigan.

d. Proposed Changes to Priority for Sensitized Candidates
The National Organ Transplant Act (NOTA) of 1984 called for additional consideration to be given to candidates who face biological difficulties in obtaining a transplant. Candidates who are immunologically sensitized through events such as prior transplant, blood transfusion, or prior pregnancy, are unable to receive transplants from some or most organ donors due to immunologic incompatibility. The current kidney allocation system recognizes and attempts to address these barriers by awarding four points to candidates who have a calculated panel reactive antibody greater than or equal to 80% and by prioritizing highly sensitized candidates who have been waiting longer than unsensitized candidates at the local level of distribution.

The Committee examined the performance of these policies and found that they did not adequately address the needs of sensitized candidates on the waiting list. As of the end of 2010, nearly two-thirds of kidney candidates were reported as being non-sensitized (CPRA=0%), but about 11% were “very highly sensitized,” with a CPRA of 95% or higher. Though about 5% of candidates had CPRA of 100%, these extremely difficult to match candidates accounted for less than 1% of the transplants. Demographically, candidates who were younger, female, and African American tended to have a higher likelihood of being very highly sensitized (CPRA>=95%). There was only a weak relationship between blood type and CPRA, with types O and B having a slightly higher chance of being highly sensitized.

Sensitized candidates were found to wait substantially longer than unsensitized candidates, suggesting that more needs to be done to equalize waiting times between these two groups. On average, non-sensitized patients received about 17 compatible offers per year, while fully sensitized (CPRA=100%) patients received only 0.09 compatible offers per year, a 187-fold difference, in spite of the four-point advantage (Figure 8). If not for the additional priority given to sensitized candidates for zero-antigen mismatches, the decrease in offer rates would be even more dramatic for those with CPRA approaching and equal to 100%.

Additionally, candidates with CPRA greater than 95% see a marked decline in the number of compatible offers received (Figure 9). Finally, the Committee observed that the current policy may assign too much priority for candidates with CPRA scores of 80-84%, as indicated by the artificial increase in offers for this group and the substantial increase in transplants for this group (Figure 10).
Figure 8: Offers per patient-year by candidate CPRA

Figure 9: Offers per patient-year for candidates with CPRA scores greater than or equal to 95%
In consultation with the OPTN/UNOS Histocompatibility Committee, the following interventions were proposed as policy options to address the above problems:

1. Assign points for sensitization at a lower CPRA and scale these points to the level of difficulty that these candidates have in obtaining a compatible transplant.
2. Prioritize candidates who are extremely unlikely to receive a transplant due to sensitization ahead of zero-antigen mismatch transplants. The Committees determined that candidates with CPRA scores greater than or equal to 98% face far greater difficulty in obtaining a transplant and require exposure to a larger donor pool to have any chance of receiving a transplant at roughly the same time as similar unsensitized candidates.

The Committee reviewed data analyses to determine where to begin assigning points for sensitization and how to scale these points (See Appendix 1 uploaded as a separate pdf. attachment on the OPTN public comment website.). Though there are some similarities, transplant rates (Figure 10) showed a somewhat different pattern as a function of CPRA than did offer rates (Figure 8 and Figure 9). As CPRA increased from 0% to around 60%, transplant rates held constant at around 200 transplants per 1,000 patient-years, in spite of the steady decline in the offer rate. As CPRA increased beyond 60%, transplant rates decreased moderately up to a CPRA of 79%. When CPRA reached 80%, the transplant rate increased dramatically, more than doubling the rate of non-sensitized or moderately sensitized candidates, in spite of the fact that the offer rates for the 80-84% CPRA group increased only moderately. This disconnect between the transplant rate and offer rate patterns by CPRA is thought to be due to differences in transplant center offer acceptance practices.

Based on a time-to-offer analysis, the Committee found that that candidates began to experience barriers to transplant starting at a CPRA score of 20% which gradually increased with increasing sensitization until an inflection point at about 95%. Above 95%, waiting time increases more substantially due to the decreasing offer and transplant rate for these candidates. In response to these observations, the following point system, a “sliding scale” based on candidate CPRA was derived via a mathematical transformation of the offer rate patterns shown in Figure 8 and Figure 9.
<table>
<thead>
<tr>
<th>If the candidate’s CPRA score is...</th>
<th>Then the candidate receives this many points...</th>
</tr>
</thead>
<tbody>
<tr>
<td>x=0</td>
<td>0.00</td>
</tr>
<tr>
<td>0&lt;x&lt;10</td>
<td>0.00</td>
</tr>
<tr>
<td>10&lt;=x&lt;20</td>
<td>0.00</td>
</tr>
<tr>
<td>20&lt;=x&lt;30</td>
<td>0.08</td>
</tr>
<tr>
<td>30&lt;=x&lt;40</td>
<td>0.21</td>
</tr>
<tr>
<td>40&lt;=x&lt;50</td>
<td>0.34</td>
</tr>
<tr>
<td>50&lt;=x&lt;60</td>
<td>0.48</td>
</tr>
<tr>
<td>60&lt;=x&lt;70</td>
<td>0.81</td>
</tr>
<tr>
<td>70&lt;=x&lt;75</td>
<td>1.09</td>
</tr>
<tr>
<td>75&lt;=x&lt;80</td>
<td>1.58</td>
</tr>
<tr>
<td>80&lt;=x&lt;85</td>
<td>2.46</td>
</tr>
<tr>
<td>85&lt;=x&lt;90</td>
<td>4.05</td>
</tr>
<tr>
<td>90&lt;=x&lt;95</td>
<td>6.71</td>
</tr>
<tr>
<td>95&lt;=x&lt;96</td>
<td>10.82</td>
</tr>
<tr>
<td>96&lt;=x&lt;97</td>
<td>12.17</td>
</tr>
<tr>
<td>97&lt;=x&lt;98</td>
<td>17.30</td>
</tr>
<tr>
<td>98&lt;=x&lt;99</td>
<td>24.40</td>
</tr>
<tr>
<td>99&lt;=x&lt;100</td>
<td>50.09</td>
</tr>
<tr>
<td>100</td>
<td>202.10</td>
</tr>
</tbody>
</table>

Even with such a substantial increase in points (24.40 points for CPRA of 98; 50.09 points for CPRA of 99, 202.10 points for CPRA of 100), candidates with CPRA scores greater than or equal to 98% still cannot hope to achieve a transplant rate similar to unsensitized candidates based on an increased number of points alone. If there are few local, compatible donors available for these candidates, awarding a large number of points to put them at the top of their local list will have very little impact. Due to their level of sensitization, these candidates require access to a larger donor pool in addition to priority within their donation service area.

The Committee also investigated two approaches for broader sharing for candidates with CPRA scores greater than or equal to 98% (Table 4). Option 1 prioritized all candidates with CPRA scores greater than or equal to 98% ahead of zero-antigen mismatch transplants at the local, regional and national levels. Option 2 took a tiered approach to broader sharing, recognizing that candidates with CPRA scores of 100% are much less likely to receive a compatible offer than lesser sensitized candidates. Additionally, Option 2 broadened the geographic donor pool incrementally so that candidates with CPRA scores of 99% received regional priority while candidates with CPRA scores of 100% received national priority. Under Option 2, candidates with CPRA scores of 98% received local priority ahead of zero-antigen mismatch offers. Based on the findings from KPSAM (see Supporting Evidence section), the Committee selected Option 2 for this policy proposal.
Table 4: Allocation sequences considered for broader sharing for very highly sensitized candidates

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Local CPRA 98-100</td>
<td>• Local CPRA 100</td>
</tr>
<tr>
<td>• Regional CPRA 98-100</td>
<td>• Regional CPRA 100</td>
</tr>
<tr>
<td>• National CPRA 98-100</td>
<td>• National CPRA 100</td>
</tr>
<tr>
<td>• Zero mismatch classifications</td>
<td>• Local CPRA 99</td>
</tr>
<tr>
<td>• [...]</td>
<td>• Regional CPRA 99</td>
</tr>
</tbody>
</table>

As with any policy that requires sharing especially for highly sensitized candidates, concerns were raised about unforeseen positive crossmatches. Under the current allocation system, for every one offer refusal due to positive crossmatch, (among non-local offers in 2010 to candidates with CPRA of greater than or equal to 98%), there were 3.5 successful transplants for these very highly sensitized candidates. However, since the rate of offer refusal due to positive crossmatch is higher for highly sensitized candidates, the proposed policy includes additional requirements to reduce these events. Specifically, in order for a candidate with a CPRA score of 99% or 100% to receive regional or national offers, the candidate’s transplant physician and the transplant program’s HLA laboratory director would be required to review and approve the unacceptable antigens listed for the candidate.

e. Proposed Changes to Pediatric Allocation

Currently, pediatric candidates receive priority in several ways for kidneys from donors generally considered of higher quality. Specifically, candidates who are younger than 18 years at the time of the match and who have a 0-ABDR mismatch with the donor receive priority in the form of points (4 points for 0-10 years old and 3 points for 11 to 17 years old) and also categorical priority. Candidates who were younger than 18 at the time of registration receive priority ahead of all other local candidates for kidneys from donors younger than 35. This system was designed to expedite transplant for pediatric candidates by providing increased access to organs with longer estimated post-transplant function. The system has been working well and achieving its stated objectives.

As the Kidney Transplantation Committee began working to design a kidney allocation system based on KDPI, it asked the Pediatric Transplantation Committee to consider whether the donor age threshold could be converted to KDPI, a more refined measure of donor quality compared to age alone. The purpose of this change would be to maximize system flexibility. As the composition of the waiting list or the donor population changes, having the entire system based on KDPI could allow for easier changes to accommodate the changing needs of the pediatric population. After modeling various thresholds, the Pediatric Transplantation Committee recommended that the KDPI threshold be set at 0.35. With this threshold, SRTR simulation modeling has forecasted that pediatric candidates would maintain the same level of access that is experienced under the current system.

Additionally, in the proposed system, pediatric candidates would no longer receive offers for kidneys from donors with KDPI scores greater than 85%. An analysis of OPTN data determined there have been zero transplants of solitary ECD kidneys into pediatric candidates since 2007. Removing pediatric
candidates from this allocation sequence would streamline system efficiency without harming access for this patient population.

f. Proposed Changes to Blood Type Eligibility
Currently, the kidney allocation system limits the blood types that may be transplanted into each candidate as a means of maintaining equity. Blood type B kidneys must be transplanted into blood type B recipients and blood type O kidneys must be transplanted into blood type O recipients. Exceptions are made only in the case of zero antigen mismatched transplants.

In 2001, the OPTN Board of Directors approved a variance to enable the transplantation of blood type A₂ (technically, “non-A₁”) and A₂B (technically, “non-A₁B”) deceased donor kidneys into blood type B candidates. The goal of this variance was to increase the rate of transplantation in blood type B candidates by allocating these kidneys to them without negatively impacting post-transplant outcomes. Since the national median waiting time for deceased donor kidney transplantation is highest for blood type B candidates, this variance was expected to decrease an access barrier to transplantation for blood type B candidates.

Since implementation, nine OPOs have participated in this variance. Published studies have found A₂ and A₂B kidneys transplanted into blood type B recipients have comparable survival rates and that this practice has shortened waiting times for this blood type.³,⁴

To be eligible to receive an A₂ or A₂B kidney, a blood type B candidate would need to have two consecutive quarterly anti-A titers performed demonstrating low isoagglutinin titers (anti-A IgG titer<1:8); any candidates with a titer value of 1:8 or higher will be excluded.

g. Proposed Changes to Kidney Payback Policy
Currently, the kidney allocation system requires an OPO that receives a kidney from another OPO for zero-antigen mismatch or for a combined organ transplant to payback a kidney to the originating OPO from the same blood type. Policy sets requirements for which types of kidneys must be offered as paybacks.

From an administrative perspective, the kidney payback system has been fraught with challenges since its implementation. Penalties for exceeding debt thresholds are levied against all transplant programs served by an OPO, even if only one program is responsible for accruing the debt. Several OPOs have reported difficulty in paying down debt because credited OPOs do not accept payback offers. The Kidney Transplantation Committee has spent considerable time hearing complaints about the payback system and has, over the years, adjusted the system to no apparent benefit. Furthermore, the benefit of shipping kidneys purely for administrative purposes is not clear. Payback kidneys tend to have more cold ischemic time than kidneys transplanted locally. For these reasons, the Committee proposes eliminating the kidney payback system entirely. Kidneys that are shared for zero antigen mismatches,

for extremely highly sensitized candidates, and for combined organ transplant would no longer incur a payback debt.

h. Proposed Regional Allocation for Higher KDPI Kidneys
Currently, kidneys from expanded criteria donors are offered first locally and candidates who elect to receive ECD kidneys are rank ordered only according to waiting time. The goal is to expedite placement of these kidneys. Unfortunately, discard rates for ECD kidneys are high and also vary widely across OPOs. Generally, OPOs with longer waiting times tend to procure and transplant more ECD kidneys than OPOs with shorter waiting times. This suggests that demand drives decision making on whether to utilize these kidneys more so than clinical utility.

The Committee investigated ways to improve procurement and transplantation rates for kidneys at a high risk of discard. Among the options considered was expanding the distribution area for these kidneys so that these kidneys are offered first to a combined regional and local unit. This proposed approach would make available with less cold ischemic time those kidneys that would be discarded in one OPO due to shorter candidate waiting times but utilized in a neighboring OPO with longer waiting times.

i. Proposed Changes to Kidney Allocation Variances
Many OPOs have variances in place that allow for kidney allocation according to rules or distribution units that are different from the national policy. These variances were reviewed by the Kidney Transplantation Committee and approved by the OPTN Board of Directors over a period of over two decades. Many of these variances pre-date the OPTN Final Rule which sets requirements for variances (Figure 11).\(^5\) Briefly, the OPTN Final Rule describes variances as experimental policies designed to test allocation methods. As such, variances are to have a research design with data collection and analysis plans and an end date. Additionally, variances must adhere to the principles of policy development including being based on medical judgment, achieve best use of organs, be designed to avoid wasting organs/futile transplants, promote access, and shall not be based on a patient’s place of residence except as required under Final Rule provisions.

Section 121.8: Allocation of Organs

(g) Variances. The OPTN may develop, in accordance with § 121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of § 121.4.

(a) Policy development. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:
(1) Shall be based on sound medical judgment;
(2) Shall seek to achieve the best use of donated organs;
(3) Shall preserve the ability of a transplant program to decline an offer of an organ or

\(^5\) 42 C.F.R. §121.8
not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);  
(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;  
(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;  
(6) Shall be reviewed periodically and revised as appropriate;  
(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program; and  
(8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

Section 121.4: OPTN policies: Secretarial review and appeals  
(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act [Public Health Service Act] and the Secretary’s contract for the operation of the OPTN, including:  

Policies for the equitable allocation of cadaveric organs in accordance with 121.8

Figure 11: Excerpt from the OPTN Final Rule regarding variances

The Committee engaged in a review process of all of the existing kidney allocation variances. As with other major allocation system revisions (e.g., lung allocation, and heart allocation), the Committee decided not to carry existing variances into the new kidney allocation system with two exceptions. The Committee-sponsored alternative allocation systems to initiate waiting time from the start of dialysis and to allocate organs from A$_2$ and A$_2$B donors to blood type B candidates are being proposed as a national policy. All other variances would sunset with the implementation of a new kidney allocation system. Transplant programs may apply for new variances according to the Final Rule requirements and OPTN policies governing variances.

Transplant programs in OPOs that requested continuation of a variance were invited to submit a proposal for a transition plan which would be implemented prior to the implementation of a new kidney allocation system. As some of these variances have been in place for over 20 years, the purpose of these transition plans would be to lessen severe effects of switching from the current allocation system to the proposed allocation system. The Committee received two requests for transition plans, one from the transplant programs in Region 1, and one from the transplant programs served by Southwest Transplant Alliance in Texas.

Proposed Transition Plan for Candidates Listed in Region 1

Region 1 uses the standard distribution and allocation system with the following exceptions. For distribution, the region combines kidney waiting lists for its two OPOs - New England Organ Bank (MAOB) and LifeChoice Donor Services (CTOP) - into a single list. There are no “OPO KI” classifications on Region 1 kidney matches. Region 1 renal candidates cannot be listed at multiple programs within Region 1.
Region 1 waiting time is based upon the time a candidate has been on dialysis. This requirement to be on dialysis applies to both pediatric and adult candidates, but time cannot be accrued prior to the listing date in UNet™. Anniversary year points are not awarded to Region 1 candidates. Instead, for allocation of standard criteria donor kidneys, a maximum of eight points are assigned for time waiting if one of the following criteria is met:

- candidates 0-5 years old who have been waiting six months or more,
- candidates 6-10 years old who have been waiting 12 months or more,
- candidates 11-17 years old who have been waiting 18 months or more, and
- candidates 18 years old or older who have been waiting three years or more.

For candidates that do not meet the above criteria, waiting time points are based on the following formulas:

- 0-17 years old at the time the match is run:
  \[ \text{ABS} \left( \frac{(1 - \left( \frac{\text{(days waiting)}}{\text{threshold}}} \right)^2)}{64.0} + 8.0 \right) - 16.0 \]
  \[ \text{threshold} = 180, 365, \text{or} 545 \text{ days as defined above by candidate age} \]

- 18 years old or older at the time the match is run:
  \[ (8.0/3.0) \times \frac{\text{(days waiting)}}{365.0} \]

Additionally, seven points are assigned if there are no B or DR mismatches between the patients’ and donors’ antigens. Potential recipients in Region 1 can also accrue up to a maximum of 10 “population distance points.” Population distance points are distributed according to a linear curve which is based upon population between donor hospital and the candidate’s transplant center.

The transplant programs in Region 1 propose a single stage transition plan that would reduce the maximum number of population distance points from the current of 10 points down to 6 points. Other aspects of the variance would remain in place until the transition to the new national system. Population distance points are unique to Region 1 and have significant influence on the allocation of kidneys. Reducing these points from 10 to 6 is expected to be less disruptive than a sudden, total elimination of points as would occur if no transition plan were put into place.

**Proposed Transition Plan for Candidates Listed at Programs Served by Southwest Transplant Alliance**

Southwest Transplant Alliance (TXSB) uses the standard distribution and allocation system with the following exception. For distribution of standard and expanded criteria donors, the system divides the OPO into four sub-units – Dallas area, Tyler area, El Paso area, and Galveston area. Kidneys recovered within each sub-unit are distributed, first, according to a single waiting list for the sub-unit, and then to patients within the entire OPO according to a single OPO-wide list. Candidates appear in the “Local KI” classifications if they are listed at a transplant center in the same subunit as the donor hospital.

TXSB proposes that the subunits be combined into a single local unit based on the donation service area. Potential recipients who are in the same subunit as the donor hospital would then receive three additional points during the transition period. The transition period would last until the implementation of a new national kidney allocation system.
Supporting Evidence:

The Scientific Registry of Transplant Recipients (SRTR) used the Kidney-Pancreas Simulated Allocation Model (KPSAM) to evaluate the effect of policy changes described above. The complete technical analysis is provided as Appendix 2.\(^6\)

To better determine the individual effects of the proposed policy changes, four separate simulation runs were conducted. These are referred to as N1, N2, N3, and N4 for reference purposes. Simulation run N1 represents the current kidney allocation system with results that closely mimic those actually observed in 2010. Simulation run N2 included the following proposed changes to the current allocation system: the revised definition of waiting time, allocation of A\(_2\) and A\(_2\)B kidneys to B candidates, etc. (per Table 5). Simulation run N3 includes those enhancements from N2 and also longevity matching, national priority for candidates with CPRA greater than or equal to 98%, regional sharing for kidneys with KDPI scores greater than 85%. Simulation run N4 is identical to simulation run N3 but alters the priority for candidates with CPRA greater than or equal to 98% to provide national priority for candidates with CPRA scores of 100%, regional priority for candidates with CPRA scores of 99%, and local priority for candidates with CPRA scores of 98%. The following tables summarize the proposed changes evaluated in each simulation run.

**Table 5: Kidney transplant recipients by recipient CPRA, with waitlist prevalence**

<table>
<thead>
<tr>
<th>Proposed Change</th>
<th>N1</th>
<th>N2</th>
<th>N3</th>
<th>N4</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCD allocation (defined as KDPI &lt;=0.85 for N3 and N4)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>DCD allocation</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECD allocation (defined as KDPI &gt;=0.85 for N3 and N4)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Eliminate kidney payback system</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enhanced definition of waiting time to include pre-listing time since initiation of dialysis</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waiting time based on fractional years</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A(_2)/A(_2)B donor to B candidates priority (local, regional, national)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Pediatrics cannot receive non zero mismatched ECD offers (defined as KDPI &gt;=0.85 for N3 and N4)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Longevity matching (based on KDPI and EPTS)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share KDPI 0.35 pediatric priority (donor &lt;35 years for N1, N2)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPRA sliding scale point assignment</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>National Priority for CPRA&gt;=98%</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Tiered Priority for CPRA&gt;=98%</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Regional sharing for kidneys with KDPI scores &gt;=85%</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Summary of Findings**

Simulation run N4 represents the combination of proposed changes the Committee proposes to best address the limitations of the current system and achieve the objectives of reducing discards, reducing

\(^6\) The Committee has reviewed over 50 separate simulation runs since 2004 including simulation modeling of the LYFT and age matching concepts which are no longer under consideration. To learn more about prior modeling, you may review the Committee’s reports at http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=89.
variability in access, and improving outcomes for all kidney transplant candidates. Overall, the system results in a projected total of 144,676 “life years” from the approximately 11,000 annual deceased donor kidney transplants. By comparison, the current system (N1) results in a simulated 136,296 life years, reflecting an estimated increase of 8,380 life years achieved annually for the proposed system (N4) compared to the current system. This increased is based on a projected 7.7% increase in the median life years per transplant, from 11.82 to 12.73. The new system is also expected to increase the median life years of benefit (relative to staying on the waitlist) per transplant from 5.01 to 5.27, a 5.2% increase (Table 6). In addition, the proposed system results in an increase in the number of sensitized candidates receiving transplants, especially those with very high levels of sensitization. This system also results in an increased transplant rate for African American and Hispanic candidates. These results are obtainable with a minimal increase in the rate of shipping kidneys.

Table 6: Summary Table for Simulation Runs N1-N4

<table>
<thead>
<tr>
<th>Average for 10 iterations</th>
<th>N1</th>
<th>N2</th>
<th>N3</th>
<th>N4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of candidates</td>
<td>122,669</td>
<td>122,669</td>
<td>122,669</td>
<td>122,669</td>
</tr>
<tr>
<td>(on waitlist at start or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>joining during run)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average number of primary</td>
<td>11,531</td>
<td>11,595</td>
<td>11,386</td>
<td>11,365</td>
</tr>
<tr>
<td>KI+KP transplant</td>
<td>(11,463-11,586)</td>
<td>(11,526-11,655)</td>
<td>(11,359-11,429)</td>
<td>(11,324-11,409)</td>
</tr>
<tr>
<td>recipients (min, max of</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>runs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average median lifespan</td>
<td>11.82</td>
<td>11.72</td>
<td>12.63</td>
<td>12.73</td>
</tr>
<tr>
<td>(min, max of runs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average median graft</td>
<td>8.82</td>
<td>8.8</td>
<td>8.99</td>
<td>9.1</td>
</tr>
<tr>
<td>years of life (min,</td>
<td>(8.80-8.84)</td>
<td>(8.77-8.82)</td>
<td>(8.97-9.02)</td>
<td>(9.08-9.12)</td>
</tr>
<tr>
<td>max of runs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average median extra</td>
<td>5.01</td>
<td>4.95</td>
<td>5.24</td>
<td>5.27</td>
</tr>
<tr>
<td>life-years for tx</td>
<td>(4.99-5.03)</td>
<td>(4.93-4.99)</td>
<td>(5.20-5.27)</td>
<td>(5.24-5.29)</td>
</tr>
<tr>
<td>recipient versus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>waitlist candidate (min,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>max of runs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average median LYFT per</td>
<td>5.7</td>
<td>5.65</td>
<td>5.93</td>
<td>5.97</td>
</tr>
<tr>
<td>transplant (min, max of</td>
<td>(5.68-5.72)</td>
<td>(5.63-5.69)</td>
<td>(5.89-5.96)</td>
<td>(5.95-6.0)</td>
</tr>
<tr>
<td>runs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results by Recipient Demographics
The following graphs depict the percent of candidates on the waiting list as well as the recipients under simulation runs N1-N4 by blood type, ethnicity, age, degree of zero antigen mismatches, and degree of sensitization. In these graphs, “Waitlist” indicates the percentage of the total kidney candidates on the waitlist in 2010 by each characteristic; “2010” indicates the actual, observed percentage of transplants that occurred in 2010 by each characteristic; and N1-N4 display the simulated output from KPSAM under each of the four allocation systems.
Figure 12: Kidney candidates and kidney transplant recipients by blood type

Figure 13: Kidney candidates and kidney transplant recipients by age
Figure 124: Kidney candidates and kidney transplant recipients by ethnicity

Figure 15: Kidney transplant recipients by zero antigen mismatches
Figure 16: Kidney candidates and kidney transplant recipients by CPRA

Figure 17: Kidney candidates and kidney transplant recipients where CPRA equals zero
Figure 18: Kidney candidates and kidney transplant recipients by CPRA, where CPRA is between 1% and 69%

Figure 19: Kidney candidates and kidney transplant recipients by CPRA, where CPRA is between 70% and 94%
System Effects
The percent of kidney sharing, or kidneys being transplanted in a DSA other than the DSA of procurement, is expected to increase under the proposed policy. This was anticipated, as the policy specifically adds new rules for sharing for candidates with CPRA scores of 99% or 100% and also combines local and regional allocation for kidneys with KDPI scores greater than 85%. However, the level of sharing for the proposed policy was found to be less than the level of sharing under simulation run N3.
Expected Impact on Living Donors or Living Donation:

This proposal updates the prior living organ donor policy to specify that the date of procurement, not the date of transplant, is necessary to certify a candidate as a prior living organ donor. The current policy is vague on situations where an organ is procured from a living donor but not transplanted into a recipient. These occurrences are infrequent but may be due to a change in the recipient’s health status, the discovery of disease or trauma in the donated organ, or other factors outside of the donor’s control. The proposed policy language clarifies that a candidate will be considered a prior living organ donor if they donated an organ, even if that organ did not ultimately result in a transplant.

As to effects on living donation, during the course of policy development, some professional groups raised concerns that longevity matching would lead to a substantial drop in living kidney donation for young adult candidates. The concerns cited a decline in living donor transplants shortly after implementation of the pediatric policy to give pediatric candidates priority for kidneys from donors younger than 35. The Committee reviewed this phenomenon and found that the decline in living donor transplants during this time frame was not limited to pediatric candidates and may have been partially due in part to highly publicized donor deaths and not entirely due to the implementation of the Share 35 policy.7

Some people reasoned that if candidates with EPTS scores less than or equal to 20% are able to receive a high quality kidney transplant with little waiting time, then they will be less likely to seek out a living donor. The Committee reviewed the distribution of candidates and donors and found that in every OPO, the number of candidates with EPTS scores less than or equal to 20% greatly exceeds the number of donors with KDPI scores less than or equal to 20%. This means it is highly unlikely that a candidate with no waiting time and an EPTS score less than or equal to 20% would immediately receive a kidney transplant because the demand still greatly exceeds the supply. All candidates, with the exception of those fortunate enough to receive a zero antigen mismatch transplant, will still need to wait for a deceased donor kidney transplant regardless of their EPTS score. Consequently, the Committee believes that incentives for seeking a living donor, whose kidneys are also generally of significantly higher quality than deceased donor kidneys, will not be appreciably changed by this proposal.

Expected Impact on Specific Patient Populations:

Please see the section entitled Supporting Evidence for a detailed description of expected impact by patient demographics.

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

This proposal is expected to meet the OPTN Key Goals of increasing access to transplant and improving post-transplant survival for recipients. Through the CPRA sliding scale, the enhanced definition of waiting time and incorporation of the A2/A2 kidneys for B candidates, access for minority candidates and highly sensitized candidates is expected to improve. The addition of longevity matching through KDPI and EPTS is expected to improve post-transplant survival by adding an additional 8,380 life years

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obtainable annually from the proposed allocation system. Finally, this proposal will reset kidney allocation variances to comply with the requirements set forth in the OPTN Final Rule.

**Plan for Evaluating the Proposal:**

The policy will be formally evaluated approximately 6 months post-implementation, 1 year post-implementation, and annually thereafter, or until no longer needed, as per the direction of the OPTN Kidney Transplantation Committee.

The following hypotheses, and any others subsequently requested by the Committee, will be evaluated to compare performance before versus after the implementation of the new system.

1. Is the new kidney allocation system resulting in fewer transplants considered to be severe mismatches in terms of donor and recipient age or expected longevity?
2. Has the implementation of a system incorporating longevity-matching resulted in changes in the kidney utilization patterns for candidates of different ages and/or EPTS?
3. How have offer acceptance and organ utilization rates changed after the implementation of KDPI in DonorNet® and for allocation?
4. Has the new system increased equity in access to opportunities (offers) for transplant, as well as actual transplants, for candidates with differing demographic and medical characteristics: age, ethnicity, blood type, and sensitization level (CPRA)?
5. Has access to pediatric candidates, and the quality of kidneys used in pediatric transplants, changed significantly?
6. How has the new system changed the geographic distribution of kidney transplants (local vs. regional vs. national)?
7. Has there been a significant increase in cases where kidneys are shipped but ultimately discarded or redirected due to an unexpected positive crossmatch?
8. Has the new system resulted in any (positive or negative) unintended consequences for particular patient subpopulations, or in other areas such as the rates of living kidney donation, the rates of adding candidates to the list, or the percent of candidates in inactive status?

The following metrics, and any others subsequently requested by the committee, will be evaluated to compare performance before vs. after the implementation of the new system:

- The distribution of transplants by recipient age, ethnicity, ABO, CPRA, HLA-mismatch level, diagnosis, EPTS score (after only).
- Rates of receiving kidney offers per patient-year by recipient age, waiting time, ethnicity, ABO, CPRA, HLA-mismatch level, diagnosis, EPTS score (after only).
- Transplant rates per patient-year by recipient age, ethnicity, waiting time, ABO, CPRA, HLA-mismatch level, diagnosis, EPTS score (after only).
- Organ offer acceptance rates by recipient age, ethnicity, waiting time, ABO, CPRA, EPTS score (after only).
- Time to transplant by recipient age, ethnicity, ABO, CPRA, EPTS (after only).
- Organ offer acceptance rates by KDPI and DCD/ECD/SCD
- Kidney utilization and discard rates by KDPI and DCD/ECD/SCD
- Organ offer refusal rates, refusal reasons, and utilization rates for candidates with CPRA exceeding 98%
• Distribution of transplants jointly by recipient and donor age groups
• Distribution of transplants jointly by recipient age and donor KDPI groups
• Frequency of donor blood type A\textsubscript{2} and A\textsubscript{2}B transplants into B candidates
• Geographic distribution of transplants: % local, regional, national
• Distribution of cold ischemic times for kidney transplants, in particular for high KDPI kidneys
• Estimated median post-transplant survival, and rates at 1 year post-transplant
• Rates of kidney recipients needing a retransplant, by recipient age
• Rates of kidney recipients dying with functioning grafts, by recipient age
• For cases of death with functioning graft, the average “expected remaining life years” for each transplanted kidney (e.g., projected graft half-life, per KDPI, minus actual graft usage time)

Since external factors, such as the changing donor pool, improving graft survival rates over time, and other changes in transplant policy or practice, can influence the pre and post-implementation periods differently, interpreting the apparent impact of a policy change based on a “before vs. after” analysis must be done with caution.

Additional Data Collection:

The following data fields would be added as a result of these policy changes.

• Verification that the HLA Laboratory Director and Transplant Physician approve of the listed unacceptable antigens for candidates with CPRA scores greater than or equal to 98%.
• Titer fields will be added for blood type B candidates who wish to be considered for kidneys from blood type A\textsubscript{2} or blood type A\textsubscript{2}B donors. These fields will be required to be updated between 70 and 110 days and remain below 1:8 for a candidate to remain eligible to receive incompatible blood type offers. Additionally, a field indicating that the candidate consents to receive a blood type incompatible organ would be added.
• Whether a candidate has had a prior solid organ transplant (organ type(s) and date(s)) will also need to be collected for calculating EPTS.
• The acceptable upper and lower threshold values for KDPI for each candidate will be collected.

The following data are currently collected, however the proposed policies may change how data are entered into the system.

• **Unacceptable Antigens.** Currently, candidates with CPRA scores greater than or equal to 80% receive 4 points, with no further distinction in points based on differing CPRA values. Some programs only enter enough unacceptable antigens to receive this priority. The proposed policy utilizes a sliding scale, assigning incrementally increasing points as CPRA increases, starting with CPRA of 20%. This may increase the incentive to enter all unacceptable antigens for each candidate.
• **Dialysis start date.** Current policy does not count time spent on dialysis prior to registration towards waiting time. The proposed policy would count all time spent on dialysis, including any time prior to registration, towards a candidate’s waiting time. Candidates with missing dialysis start dates at the implementation of the new system will receive time only back to registration with a GFR<=20. In particular, transplant centers will be requested to provide this historical data to ensure that such candidates receive the full waiting time credit to which they are entitled under the expanded definition of waiting time.
• Diabetes status is currently collected on the Transplant Candidate Registration (TCR) form and would now also be collected on the Waitlist. If a candidate’s diabetes status changes, it will need to be updated on Waitlist only. Transplant programs will not be able to enter “unknown” for diabetes status.

All fields necessary to calculate the donor’s KDPI are already required to run a kidney match, so this proposal does not result in additional data collection requirements for OPO’s.

**Expected Implementation Plan:**

This proposal will be considered by the Board of Directors in June 2013. If approved, the changes will be effective upon programming and notice to members.

Transplant programs should review its processes and how they may need to change to align with the new policy. Specifically, changes will likely be necessary in the following areas:

• Develop a procedure for obtaining consent for the types of kidneys (defined by upper and lower KDPI values) a newly listed candidate would be willing to accept. Existing candidates listed as unwilling to accept ECD kidneys would receive a minimum donor acceptance value for KDPI of 0% and a maximum donor acceptance value for KDPI value of 85%. Existing candidates listed as willing to accept ECD kidneys would receive a minimum donor acceptance value for KDPI of 0% and a maximum donor acceptance value for KDPI of 100%. Existing candidates listed for both ECD and SCD kidneys would receive a minimum donor acceptance value for KDPI of 0% and a maximum donor acceptance value for KDPI of 100%. Transplant programs will be able to alter these values for existing candidates.

• Create an approval and documentation process to obtain approval of unacceptable antigens from the HLA Laboratory Director and Transplant Physician or Transplant Surgeon for candidates with CPRA scores of 99% and 100%.

• Begin reviewing candidate records to ensure that all components for the EPTS score are correctly listed in UNet (i.e., correct dialysis start date, diabetes status, prior organ transplant and date of birth).

Transplant program staff and OPO staff should avail themselves of relevant educational opportunities offered through the OPTN Contractor. Webinars will be made available to explain the changes associated with this proposal. Additionally, staff should review available educational materials related to kidney donor profile index (KDPI) including a calculator and guidance document available here: [http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=80](http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=80)

In the future, the Committee plans to provide a calculator that would help patients and providers understand outcomes associated with different treatment modalities. For example, this calculator is expected to provide estimated post transplant survival for dialysis, transplant from a living donor, and transplant from a deceased donor based on the donor’s KDPI.

**Compliance Monitoring:**

UNOS Department of Evaluation and Quality (DEQ) staff reviews all deceased donor kidney match runs daily to determine if the organs were allocated according to the match run sequence as established by
kidney allocation policy and programmed into the UNet℠ system. DEQ staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews of kidney transplant programs, DEQ staff selects a sample of transplant recipient records and reviews the recipient file documentation. DEQ staff determines if the organs have been allocated in accordance with the match runs, and verifies the accuracy of data entered in UNet℠ against the recipient’s medical record. DEQ staff investigates any reports of noncompliance. DEQ requests a corrective action plan if a hospital does not comply with the requirements of Policy 3.5 and forwards the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review in a blinded fashion.

This proposal would require the following additional monitoring:

- DEQ staff will verify that records for candidates who received regional or national offers while they had CPRA scores of 99% or 100% contain documentation of approval for any unacceptable antigens.
- DEQ staff will verify that records for blood type B candidates who received blood type non-A1 or non-A1B kidneys include documentation of consent to receive the incompatible blood type kidney.
- During on-site reviews, DEQ staff will select a sample of transplant recipient records, and review the documentation to verify that each contains a KPDI score consent, that contains all of the following for candidates registered after the implementation date of the allocation system:
  - The recipient’s signature
  - The date the recipient signed
  - The KDPI scores the recipient would be willing to consider
- For candidates registered prior to the implementation date of the allocation system:
  - If there is documented consent to receive an ECD kidney, the candidate will be considered to have consented to receive kidneys with KDPI scores of 0-100
  - If there is no documented consent for ECD or specific KDPI scores, the candidate will be assumed to consent to a kidney with a KDPI score of 0-85

In Recognition:

The development of this proposal is the result of nine years of collaborative effort. The OPTN wishes to thank the following individuals who contributed to this proposal by serving on either the Kidney Allocation Review Subcommittee or the Kidney Transplantation Committee during this time.

Mark Aeder, MD; Margo Akerman, MS; Denise Alveranga, MD, FACP, FASN; Sandra Amaral, MD; Kenneth Andreoni, MD; Clyde Barker, MD; Bryan Becker, MD; Adam Bingaman, MD, PhD; James Bowman III, MD; Kenneth Brayman, MD, PhD, FACS; Eileen Brewer, MD; William Bry, MD; James Burdick, MD; David Burgio, MPA, LFACHE; Stephan Busque, MD, FRCSC; Michael Cecka, PhD; Blanche Chavers, MD; Dolph Chianchiano, JD, MPA; Laura Christensen, MS; Ari Cohen, MD; Fernando Cosio, MD; Gabriel Danovitch, MD, MB, LRCP, MRCS; Richard DeSanto; Noelle Dimitri, LICSW; Dale Distant, MD; Viken Douzdjian, MD; Pang-Yen Fan, MD; Gregory Fant, PhD; Harold Fassnacht, JD; Erik Finger, MD, PhD; Bernard Fischbach, MD; Richard Formica, Jr., MD; Mark Fox, MD, PhD, MPH; Adam Frank, MD; Jonathan Fridell, MD; John Friedewald, MD; Michael Gallichio, MD; Elisa Gladstone, MPH; Nathan Goodrich, MS; Paul Gores, MD; Oscar Grandas, MD; Stuart Greenstein, MD, FACS; Albin Gritsch, MD; Rainer Gresssner, MD; Sundaram Hariharan, MD; Erica Hartmann, MD; Daniel Hayes, MD; Randall Heyn-Lamb, RN, BSN,
Policy Proposal:

At the time of this proposal, the OPTN had just completed a major initiative to rewrite the OPTN policies in plain language and to organize them logically. Because of the breadth of this proposal, the policy language for this proposal is written in the new format. The following policies were moved to other sections during the plain language policy rewrite and therefore do not appear in this proposal: 3.5.3.1, 3.5.3.3, 3.5.4, 3.5.9.1, 3.5.9.2, 3.5.11.2, 3.5.14, 3.5.15, 3.5.16, and 3.5.17. For more information, the plain language policy rewrite is available at [http://optn.transplant.hrsa.gov/plainlanguage.asp](http://optn.transplant.hrsa.gov/plainlanguage.asp).

Additionally, the following sections were rewritten as part of the plain language rewrite and do not represent substantive changes as part of this proposal: 3.5.1 and 3.5.2, 3.5.6(E), 3.5.7(A), and 3.5.7(B).
Policy 3.5: Allocation of Kidneys

3.5.1 Calculated Panel Reactive Antibody

Calculated Panel Reactive Antibody (CPRA) is the percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. In order list an unacceptable antigen, the Transplant Hospital must do at least one of the following:

- Define the criteria for unacceptable antigens that are considered as contraindications for transplantation. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, as well as considerations for unexpected positive crossmatches and other circumstances.
- Base unacceptable antigens on laboratory detection of HLA specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant Hospitals may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches. CPRA will be calculated automatically when a Transplant Hospital reports unacceptable antigens to the OPTN Contractor. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

3.5.2 Exceptions

After receiving an organ offer from a donor in the same local unit, a candidate’s physician may use his medical judgment to transplant a candidate out of sequence due to medical urgency.
If there is more than one kidney transplant program in the local unit, then the candidate’s physician must receive agreement from the other kidney transplant programs in the local unit and must maintain documentation of this decision in the candidate’s medical record.

### 3.5.3 Points

Candidates receive points according to Table 3.5-1: *Kidney Points*.

**Table 3.5-1: Kidney Points**

<table>
<thead>
<tr>
<th>If the candidate is...</th>
<th>And the following allocation sequence is used...</th>
<th>Then the candidate receives this many points...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed for transplant and meets the qualifying criteria described in Policy 3.5.4 <em>Waiting Time</em></td>
<td>3.5.6.1, 3.5.6.2, 3.5.6.3, or 3.5.6.4</td>
<td>1/365 points for each day since the qualifying criteria in Policy 3.5.4 <em>Waiting Time</em></td>
</tr>
<tr>
<td>Aged 0-10 at time of match and a 0-ABDR mismatch with the donor</td>
<td>3.5.6.1, 3.5.6.2, or 3.5.6.3</td>
<td>4 points</td>
</tr>
<tr>
<td>Aged 11-17 at time of match and a 0-ABDR mismatch with the donor</td>
<td>3.5.6.1, 3.5.6.2, or 3.5.6.3</td>
<td>3 points</td>
</tr>
<tr>
<td>Aged 0-10 at time of match and donor has a KDPI score &lt;35%</td>
<td>3.5.6.1 or 3.5.6.2</td>
<td>1 point</td>
</tr>
<tr>
<td>A prior living donor</td>
<td>3.5.6.1, 3.5.6.2, or 3.5.6.3</td>
<td>4 points</td>
</tr>
<tr>
<td>Sensitized (CPRA at least 20%)</td>
<td>3.5.6.1, 3.5.6.2, or 3.5.6.3</td>
<td>See Table 3.5-2: <em>Points for CPRA</em></td>
</tr>
<tr>
<td>Share a single HLA-DR mismatch with the donor*</td>
<td>3.5.6.1, 3.5.6.2, or 3.5.6.3</td>
<td>1 point</td>
</tr>
<tr>
<td>Share a zero HLA-DR mismatch with the donor*</td>
<td>3.5.6.1, 3.5.6.2, or 3.5.6.3</td>
<td>2 points</td>
</tr>
</tbody>
</table>

*Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed “homozygous” at that locus.*
### Table 3.5-2: Points for CPRA

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

3.5.4 Waiting Time

#### 3.5.4.1 Waiting Time for Candidates Listed After Age 18

If a candidate is 18 years of age or older on the date he is registered for a kidney, then the candidate’s waiting time is based on the earlier of the following:

1. The candidate’s registration date with a measured or calculated creatinine clearance or glomerular filtration rate (GFR), less than or equal to 20 ml/min.
2. The date after registration that a candidate’s measured or calculated creatinine clearance or GFR becomes less than or equal to 20 ml/min.
3. The date that the candidate began dialysis that is regularly administered to an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

For candidates who have received a previous kidney transplant, only post-transplant dates for the above qualifying criteria (#1-3 above) apply.

#### 3.5.4.2 Waiting Time for Candidates Listed Prior to Age 18

If a candidate is younger than 18 years of age on the date he is registered for a kidney, the candidate’s waiting time is based on the earlier of the following:

1. The date that the candidate registered regardless of clinical criteria.
2. The date that the candidate began dialysis that is regularly administered to an ESRD patient in a hospital based, independent non-hospital based or home setting.

For candidates who have received a previous kidney transplant, only post-transplant dates for the above qualifying criteria (#1-2 above) apply.

3.5.5 Classification Notes

3.5.5.1 Candidate Classifications

Each candidate registered on the kidney waiting list receives an Estimated Post Transplant Survival (EPTS) score. EPTS is based on four factors: candidate time on dialysis since the last transplant, diabetes status (either Type 1 or Type 2), any prior solid organ transplant, and candidate age. Each candidate’s EPTS score is calculated at time of registration. All candidate EPTS scores are updated every 13 weeks. The reference population used to determine the top 20% EPTS threshold is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

A candidate’s EPTS score is equal to:

\[
0.047 \times \text{MAX}(\text{Age} - 25, 0) + \\
-0.015 \times \text{Diabetes} \times \text{MAX}(\text{Age} - 25, 0) + \\
0.398 \times \text{Prior Organ Transplant} + \\
-0.237 \times \text{Diabetes} \times \text{Prior Organ Transplant} + \\
0.315 \times \log(\text{Years on Dialysis} + 1) + \\
-0.099 \times \text{Diabetes} \times \log(\text{Years on Dialysis} + 1) + \\
0.130 \times (\text{Years on Dialysis} = 0) + \\
-0.348 \times \text{Diabetes} \times (\text{Years on Dialysis} = 0) + \\
1.262 \times \text{Diabetes}
\]

The following factors in the EPTS calculation are binary indicators: diabetes, prior organ transplant, years on dialysis=0. If a binary indicator is true, then it is replaced by a value of 1.0 in the calculation; otherwise, it is replaced by 0. Fractional calendar years are used for candidate’s age and years on dialysis.

3.5.5.2 Donor Classifications

Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The donor characteristics used to calculate KDRI are provided in Table 3.5-3: KDRI Factors.
To calculate KDRI, sum each of the applicable KDRI score components in Table 3.5-3, and then apply the antilog (base e) function to this sum. Divide the KDRI by the median KDRI value of the most recent donor reference population, and determine the KDPI using the KDRI-to-KDPI mapping table made available by the OPTN Contractor.

The KDPI used for allocation is based on the most recent values of donor characteristics (e.g., the latest serum creatinine) reported to the OPTN Contractor prior to running a match.

### Table 3.5-3: KDRI Factors

<table>
<thead>
<tr>
<th>This donor Characteristic...</th>
<th>Applies to...</th>
<th>KDRI score component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (integer years)</td>
<td>All donors</td>
<td>0.0128*(age-40)</td>
</tr>
<tr>
<td></td>
<td>Donors with age &lt; 18</td>
<td>-0.0194*(age-18)</td>
</tr>
<tr>
<td></td>
<td>Donors with age &gt; 50</td>
<td>0.0107*(age-50)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>African American donors</td>
<td>0.1790</td>
</tr>
<tr>
<td>Creatinine (mg/dl)</td>
<td>All donors</td>
<td>0.2200*( creatinine - 1)</td>
</tr>
<tr>
<td></td>
<td>Donors with creatinine &gt; 1.5</td>
<td>-0.2090*( creatinine - 1.5)</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>Hypertensive donors</td>
<td>0.1260</td>
</tr>
<tr>
<td>History of Diabetes</td>
<td>Diabetic donors</td>
<td>0.1300</td>
</tr>
<tr>
<td>Cause of Death</td>
<td>Donors with cerebrovascular accident as cause of death</td>
<td>0.0881</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>All donors</td>
<td>-0.0464*(height -170) / 10</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>All donors with weight &lt; 80 kg</td>
<td>-0.0199*(weight - 80) / 5</td>
</tr>
<tr>
<td>Donor type</td>
<td>DCD donors</td>
<td>0.1330</td>
</tr>
<tr>
<td>HCV status</td>
<td>HCV positive donors</td>
<td>0.2400</td>
</tr>
</tbody>
</table>
The reference population used to determine the KDRI-to-KDPI mapping is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

The KDPI is the percentage of donors in the reference population that have a KDRI less than or equal to this donor's KDRI. This percentage is rounded to the nearest integer.

3.5.5.3 Consent for Kidneys Based on KDPI
Prior to receiving offers, transplant programs must obtain consent from each kidney candidate regarding the KDPI scores he or she would be willing to consider.

3.5.5.4 Sorting Within Each Classification
Within each classification, candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate’s registration (oldest to most recent)

3.5.5.5 Blood Type Permissibility
Transplants are restricted by blood type in certain circumstances.

- Blood type O kidneys must be transplanted only into blood group O candidates.
  - Exception: In cases of offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.

- Blood type B kidneys must be transplanted only into blood type B candidates
  - Exception: In cases of offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.

- Blood type non-A\textsubscript{1} (i.e., A\textsubscript{2}) and non-A\textsubscript{1}B (i.e., A\textsubscript{2}B) kidneys may be transplanted into candidates with blood type B who meet the following criteria.
  - Indication that the candidate consents to accept a blood type incompatible kidney
  - At least two anti-A titer values must have been entered for the candidate’s titer history at least 70 days apart but no more than 110 days apart with the most recent value within the last 110 days or the candidate becomes ineligible.
  - No anti-A titer value(s) of 1:8 or greater in the candidate’s titer history. Candidates with titer value(s) of 1:8 or greater will become permanently ineligible.

Kidney candidate and donor blood types are matched according to Table 3.5-4: Blood Typing for Kidney Allocation. Fields with a “●” indicate identical blood type matches. Fields with a “◇” indicate non-identical blood type matches. Fields with a “○” indicate incompatible (and
therefore, impermissible) blood type matches. Fields with a “*” indicate permissible blood type matches only if the candidate is 0 ABDR mismatch, otherwise the match is not permissible. Fields with a “**” indicate compatible blood type matches only if the candidate is non-A1/non-A1B eligible, otherwise the match is not permissible.

Table 3.5-4: Blood Typing for Kidney Allocation

<table>
<thead>
<tr>
<th>Donor’s Blood Type</th>
<th>Candidate is O</th>
<th>Candidate is A</th>
<th>Candidate is B</th>
<th>Candidate is AB</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>●</td>
<td>●*</td>
<td>●*</td>
<td>●*</td>
</tr>
<tr>
<td>A</td>
<td>○</td>
<td>●</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>A, Non-A1</td>
<td>○</td>
<td>●</td>
<td>●**</td>
<td>○</td>
</tr>
<tr>
<td>B</td>
<td>○</td>
<td>○</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>AB</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>●</td>
</tr>
<tr>
<td>AB, Non-A1B</td>
<td>○</td>
<td>○</td>
<td>●**</td>
<td>●</td>
</tr>
</tbody>
</table>

3.5.5.6 Prior Living Organ Donors

A candidate will be classified as a prior living donor and receive priority for each kidney registration if all of the following conditions are met:

1. The candidate donated at least one of the following for transplantation within the United States or its territories:
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.

2. The candidate’s physician reports all of the following information to the OPTN Contractor:
   - The name of the recipient or intended recipient of the donated organ or organ segment
   - The recipient’s or intended recipient’s Transplant Hospital
   - The date the donated organ was procured

3.5.5.7 Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% may receive offers in allocation classifications 1-5 in allocation sequences 3.5.6.1 - 3.5.6.4, the transplant program’s HLA laboratory director and the candidate’s transplant physician must review and sign a written approval of the unacceptable antigens listed for the candidate. The Transplant Hospital must document this approval in the candidate’s medical record.
### 3.5.6 Kidney Allocation Classifications and Rankings

#### 3.5.6.1 Allocation of Kidneys from Donors with KDPI less than or equal to 20%

Kidneys from donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates in the following order:

Table 3.5-5: Allocation of Kidneys from Donors with KDPI less than or equal to 20%

<table>
<thead>
<tr>
<th>Classification</th>
<th>Candidates that are within the...</th>
<th>And are...</th>
<th>When the donor is this blood type...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 100%, blood type identical or permissible</td>
<td>Any</td>
</tr>
<tr>
<td>2</td>
<td>Donor hospital’s region</td>
<td>CPRA equal to 100%, blood type identical or permissible</td>
<td>Any</td>
</tr>
<tr>
<td>3</td>
<td>Nation</td>
<td>CPRA equal to 100%, blood type identical or permissible</td>
<td>Any</td>
</tr>
<tr>
<td>4</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 99%, blood type identical or permissible</td>
<td>Any</td>
</tr>
<tr>
<td>5</td>
<td>Donor hospital’s region</td>
<td>CPRA equal to 99%, blood type identical or permissible</td>
<td>Any</td>
</tr>
<tr>
<td>6</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 98%, blood type identical or permissible</td>
<td>Any</td>
</tr>
<tr>
<td>7</td>
<td>Donor hospital’s local unit</td>
<td>Top 20% EPTS, 0-ABDR mismatch, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>8</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>9</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>10</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>11</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>12</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>13</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>When the donor is this blood type...</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of match, and blood type identical</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>15</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>16</td>
<td>Donor hospital’s local unit</td>
<td>Top 20% EPTS, 0-ABDR mismatch, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>17</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>18</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>19</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>20</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>21</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>22</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>23</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>24</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>25</td>
<td>Donor hospital’s local unit</td>
<td>Top 20% EPTS, 0-ABDR mismatch, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>26</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>When the donor is this blood type...</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>27</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>28</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>29</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>30</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>31</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>32</td>
<td>Donor hospital’s region</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>33</td>
<td>Nation</td>
<td>Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>34</td>
<td>Donor hospital’s local unit</td>
<td>Prior living donor, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>35</td>
<td>Donor hospital’s local unit</td>
<td>Registered prior to 18 years old, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>36</td>
<td>Donor hospital’s local unit</td>
<td>Top 20% EPTS, blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>37</td>
<td>Donor hospital’s local unit</td>
<td>Top 20% EPTS, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>38</td>
<td>Donor hospital’s local unit</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>39</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>40</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>41</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of</td>
<td>Any</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>When the donor is this blood type...</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td></td>
<td>match, and blood type identical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>43</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>44</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>45</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>46</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>47</td>
<td>Donor hospital’s local unit</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>48</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>49</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>50</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>51</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>52</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>53</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time</td>
<td>O</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>When the donor is this blood type...</td>
</tr>
<tr>
<td>--------------------</td>
<td>-----------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of match, and blood type B</td>
<td></td>
</tr>
<tr>
<td>54</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>55</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>56</td>
<td>Donor hospital’s local unit</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>57</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>58</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>59</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>60</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>61</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>62</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>63</td>
<td>Donor hospital’s region</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>64</td>
<td>Nation</td>
<td>EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
</tbody>
</table>
### 3.5.6.2 Allocation of Kidneys from Donors with KDPI Scores Greater than 20% but less 35%

Kidneys from donors with KDPI scores greater than 20% but less than 35% are allocated to candidates in the following order:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Candidates that are within the...</th>
<th>And are...</th>
<th>When the donor is this blood type...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 100%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>2</td>
<td>Donor hospital’s region</td>
<td>CPRA equal to 100%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>3</td>
<td>Nation</td>
<td>CPRA equal to 100%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>4</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 99%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>5</td>
<td>Donor hospital’s region</td>
<td>CPRA equal to 99%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>6</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 98%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>When the donor is this blood type...</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>7</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>8</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>9</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>10</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>11</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>12</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>13</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>14</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>15</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>16</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type B</td>
<td>O</td>
</tr>
<tr>
<td>17</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>18</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>19</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>20</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
</tbody>
</table>
| Classification | Candidates that are within the... | And are... | When the donor is this blood type...
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>22</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>23</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>24</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>25</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>26</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>27</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>28</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>29</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>30</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>31</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>32</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>33</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>34</td>
<td>Donor hospital’s local unit</td>
<td>Prior living donor, blood type permissible or</td>
<td>Any</td>
</tr>
</tbody>
</table>
### 3.5.6.3 Allocation of Kidneys from Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less or equal to 85% are allocated to candidates in the following order:

Table 3.5-7: Allocation of Kidneys from Donors with KDPI >=35% and <=85%

<table>
<thead>
<tr>
<th>Classification</th>
<th>Candidates that are within the...</th>
<th>And are...</th>
<th>When the donor is this blood type...</th>
</tr>
</thead>
<tbody>
<tr>
<td>35</td>
<td>Donor hospital’s local unit</td>
<td>Registered prior to 18 years old, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>36</td>
<td>Donor hospital’s local unit</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>37</td>
<td>Donor hospital’s local unit</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>38</td>
<td>Donor hospital’s region</td>
<td>Registered prior to 18 years old, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>39</td>
<td>Donor hospital’s region</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>40</td>
<td>Donor hospital’s region</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>41</td>
<td>Nation</td>
<td>Registered prior to 18 years old, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>42</td>
<td>Nation</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>43</td>
<td>Nation</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>And the donor is this blood type</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>and blood type identical</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>10</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>11</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>12</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>13</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>14</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>15</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>16</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>17</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>18</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>19</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>20</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>21</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>And the donor is this blood type</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------</td>
<td>------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>22</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>23</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>24</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>25</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>26</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>27</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>28</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>29</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>30</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>31</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>32</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>33</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>34</td>
<td>Donor hospital’s local unit</td>
<td>Prior living donor, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>35</td>
<td>Donor hospital’s local unit</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>36</td>
<td>Donor hospital’s local unit</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>Any</td>
</tr>
</tbody>
</table>
3.5.6.4 Allocation of Kidneys from Donors with KDPI Scores Greater than 85%

Kidneys from donors with KDPI scores greater than 85% are allocated to candidates in the following order:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Candidates that are within the...</th>
<th>And are...</th>
<th>And the donor is this blood type...</th>
</tr>
</thead>
<tbody>
<tr>
<td>37</td>
<td>Donor hospital’s region</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>38</td>
<td>Donor hospital’s region</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>39</td>
<td>Nation</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>40</td>
<td>Nation</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>Any</td>
</tr>
</tbody>
</table>

Table 3.5-8: Allocation of Kidneys from Donors with KDPI Scores >85%

<table>
<thead>
<tr>
<th>Classification</th>
<th>Candidates that are within the...</th>
<th>And are...</th>
<th>And the donor is this blood type...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 100%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>2</td>
<td>Donor hospital’s region</td>
<td>CPRA equal to 100%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>3</td>
<td>Nation</td>
<td>CPRA equal to 100%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>4</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 99%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>5</td>
<td>Donor hospital’s region</td>
<td>CPRA equal to 99%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>6</td>
<td>Donor hospital’s local unit</td>
<td>CPRA equal to 98%, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>7</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type permissible or identical</td>
<td>Any</td>
</tr>
<tr>
<td>8</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>9</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>10</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>11</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical</td>
<td>Any</td>
</tr>
<tr>
<td>Classification</td>
<td>Candidates that are within the...</td>
<td>And are...</td>
<td>And the donor is this blood type...</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
<td>------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>12</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type B</td>
<td>O</td>
</tr>
<tr>
<td>13</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>14</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>15</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>16</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B</td>
<td>O</td>
</tr>
<tr>
<td>17</td>
<td>Donor hospital’s local unit</td>
<td>0-ABDR mismatch, blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>18</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>19</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>20</td>
<td>Donor hospital’s region</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>21</td>
<td>Nation</td>
<td>0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible</td>
<td>Any</td>
</tr>
<tr>
<td>22</td>
<td>Donor hospital’s region</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>23</td>
<td>Donor hospital’s region</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>any</td>
</tr>
<tr>
<td>24</td>
<td>Nation</td>
<td>Blood type B</td>
<td>A2 or A2B</td>
</tr>
<tr>
<td>25</td>
<td>Nation</td>
<td>All remaining candidates, blood type permissible or identical</td>
<td>any</td>
</tr>
</tbody>
</table>

### 3.5.6.5 Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in Policies 3.5.6.1 Allocation of Kidneys from Donors with KDPI less than or equal to 20%- 3.5.6.4 Allocation of Kidneys from Donors with KDPI Scores Greater than 85% before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the donor meets at least two of the following criteria:

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

### 3.5.7 Administrative Rules

#### 3.5.7.1 Mandatory Sharing

Kidneys shared as 0-ABDR mismatches or for candidates with CPRA greater than or equal to 99% in classifications 1-5 in allocation sequences 3.5.6.1 through 3.5.6.4 must be offered within the following time limits:

<table>
<thead>
<tr>
<th>If the donor is...</th>
<th>And must make at least this many offers to identified 0-ABDR mismatch candidates...</th>
<th>Then the OPO must offer the kidneys within this many hours of procurement...</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI &lt; 85%</td>
<td>10</td>
<td>8 hours</td>
</tr>
<tr>
<td>KDPI &gt; 85%</td>
<td>5</td>
<td>3 hours</td>
</tr>
</tbody>
</table>

#### 3.5.7.2 Choice of Right versus Left Donor Kidney

If both kidneys from a donor are transplantable, the Transplant Hospital that is offered a kidney for a candidate may select which of the two kidneys it will receive. The Transplant Hospital which received the offer for the candidate with higher priority on the waiting list will have selection preference.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% in classifications 1-5 in allocation sequences 3.5.6.1 through 3.5.6.4, or to a combined kidney and non-renal organ candidate, the Host OPO determines whether to offer the left or the right kidney.

#### 3.5.7.3 Regional and National Kidney Offers

If a non 0-ABDR mismatched kidney is not placed in the donor hospital’s local unit, the OPO must contact the OPTN Contractor to assist with regional or national placement.

### 3.5.8 Variances

*Reserved*

**History**

**Notes**

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• For membership and personnel requirements for kidney programs, see the OPTN Bylaws, Appendix E.
Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion

**Affected Policies and Bylaws:** Policy 3.8.7.2 (Accrual of Waiting Time); Policy 3.8.7.4 (Process for Re-Allocating Islets); Policy 3.8.7.5 (Removal from the Pancreas Islet Waiting List); Section G.4 (Requirements for Designated Pancreatic Islet Transplant Programs) in Appendix G of the OPTN Bylaws; and, Section 1.2.D (Registration Fees) in Article I of the OPTN Bylaws

**Pancreas Transplantation Committee**

The goal of this proposal is to require the accurate and timely reporting of every islet infusion to the OPTN Contractor and to update language in policies and bylaws to reflect current practice for reporting islet infusions and outcomes information. Currently, islet Transplant Programs are not required to report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have implications for patient safety or disease transmission. This proposal:

1. Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
2. Removes outdated requirements in the bylaws for submitting islet logs.
3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed from the waiting list for transplant and immediately re-registered for another infusion.

**Affected Groups**
- Transplant Administrators
- Transplant Data Coordinators
- Transplant Physicians/Surgeons
- Transplant Program Directors
- Organ Recipients

**Number of Potential Candidates Affected**
In 2011, there were approximately 70 islet recipients. Islet recipients benefit from an accurate and timely reporting of each islet infusion because it allows for more efficient notification of patient safety or disease transmission events.

**Compliance with OPTN Strategic Goals and Final Rule**
This proposal addresses the OPTN Strategic Plan goal to promote transplant patient safety. By having accurate and timely reporting of every islet infusion, it will be easier for both Members and the OPTN Contractor’s patient safety and disease transmission staff to notify the islet program and recipient of any potential patient safety or disease transmission events. This proposal also addresses the OPTN Strategic Plan goal to promote the efficient management of the OPTN by aligning the process for reporting islet transplants with the process and timeframes for reporting all other organ transplants.
Specific Request for Comment
Does this proposal make clear that islet candidates can still accrue waiting time through three islet infusions, even though they must now be removed from the waiting list within 24 hours of each infusion instead of only after the third infusion?
Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion

Affected Policy and Bylaws: Policy 3.8.7.2 (Accrual of Waiting Time); Policy 3.8.7.4 (Process for Re-Allocating Islets); Policy 3.8.7.5 (Removal from the Pancreas Islet Waiting List); Section G.4 (Requirements for Designated Pancreatic Islet Transplant Programs) in Appendix G of the OPTN Bylaws; and, Section 1.2.D (Registration Fees) in Article I of the OPTN Bylaws

Pancreas Transplantation Committee

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The goal of this proposal is to require the accurate and timely reporting of every islet infusion to the OPTN Contractor and to update language in policies and bylaws to reflect current practice for reporting islet infusions and outcomes information. Currently, islet Transplant Programs are not required to report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have implications for patient safety or disease transmission. This proposal:

1. Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
2. Removes outdated requirements in the bylaws for submitting islet logs.
3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed from the waiting list for transplant and immediately re-registered for another infusion

Background and Significance of the Proposal:

Currently, islet policy allows an islet candidate to retain waiting time through three infusions. The islet Transplant Program has to remove the candidate from the waiting list only after the third islet infusion. The bylaws require that each transplant hospital submit islet logs accounting for every pancreas accepted for islets at the hospital, but those logs have never been collected. As a result, the OPTN Contractor does not have an official avenue for tracking every islet infusion.

The UNet℠ system already contains a process for removing and automatically re-registering an islet candidate. When a Transplant Program removes a pancreas islet (PI) candidate from the waiting list, the UNet℠ system asks the Transplant Program “Re-List Candidate?” if the number of islet infusions for that candidate’s registration is fewer than three. If the transplant hospital selects “Yes” as a response, then the UNet℠ system adds the candidate back to the PI waiting list, retaining the same waiting time the candidate had upon removal. Therefore, the OPTN Contractor already has a programmed solution in the UNet℠ system that would allow an islet Transplant Program to remove a candidate from the PI list after each infusion, but still allow the candidate to retain waiting time through three infusions.

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1 UNet℠ is a network of transplant applications, developed by the OPTN Contractor, that are interconnected to provide for the candidate waiting list, the organ placement process, data collection, and data security.
Currently, when a Transplant Program makes use of this process, the UNet℠ system does not create an additional invoice for the second or third registration. However, when a Transplant Program registers an islet candidate to the waiting list for a second or third infusion, but without using this automatic re-registration functionality, the UNet℠ system creates an additional registration fee. The Pancreas Transplantation Committee (the “Committee”) is proposing new bylaws language to reflect the current programming but requests public comment on this automated scenario. The Committee believes that a single registration fee for three infusions is appropriate, because the transplant is not complete until the candidate has received enough islets to become insulin independent, which often requires more than one infusion. Additionally, the cost to change the programming is likely to be far greater than the revenue generated by the additional fees charged for the second and third islet infusions, because islet volume is so small.

The Committee considered the following potential revisions to islet policies and bylaws:

- Require reporting to the OPTN Contractor within 24 hours of every infusion (but still allow waiting time to accrue up to and including three infusions).
- Clarify that each islet registration (as opposed to candidate) can retain waiting time through three islet infusions.
- Remove language in the bylaws about islet logs.
- Add language in the bylaws explaining the current programming that does not create an additional registration fee when an islet candidate is removed for transplant and concurrently re-listed using the process described in the paragraph above.

The Committee agreed that the changes considered would improve the process for tracking islet infusions.

The Committee also considered the impact on patient notification due to registration on and removal from the waiting list. Policy 3.2.8 (Patient Notification) requires that Transplant Hospitals notify patients in writing within 10 business days of the patient’s registration on the waiting list. Islet programs would likely need to send a letter every time they added an islet candidate to the waiting list. The Committee thought it appropriate for Transplant Hospitals to inform candidates that they were still on the waiting list and had the potential to receive islet offers. The Committee thought the burden on the islet program to inform candidates that they were still on the waiting list, would be small because of low volume. Furthermore, the Committee did not want to create additional exceptions for islet transplantation. The reason for allowing islet candidates to retain waiting time through three infusions was a clinical one. If islet candidates could receive more than one infusion in close succession, then they may need only one course of induction. These same arguments do not apply to exceptions to administrative processes like patient notification.

In general, this proposal better aligns the process for tracking islet infusions with the processes for tracking other organs. The proposal also is the first step in being able to compare outcomes between islets and whole pancreas transplantation. After the Committee has an accurate count of the number of islet infusions, full reporting of the recipients who received infusions, and which deceased donors donated islets, then the Committee can devise methods for comparing demographic and outcomes data between whole pancreas and islet transplantation.

The Committee considered leaving the islet policies and bylaws as is. The Committee ultimately decided against that approach, because an islet is the only organ that the OPTN Contractor cannot fully track. The Committee believes that if accurate accounting of other organs is important, then the same
arguments would apply for islets. Additionally, the fact that the islet logs were not being collected showed that it was not an effective way for islet data to be collected. Because a method for tracking each islet infusion was already programmed and some islet programs were already reporting each islet infusion using that method, the Committee decided to require that every infusion be reported in the UNet™ system, which is similar to what is required for every other organ.

In revising the islet policy, the Committee removed reference to Policy 6.4.1 (Exportation) in Policy 3.8.7.4. In June, 2012, the OPTN/UNOS Board of Directors deleted Policy 6.4.1 and on September 1, 2012, the content in Policy 6.4.1 became part of Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members). Policy 3.8.7.4 already references Policy 3.2.1.4.

On July 30, 2012, the Committee voted by telephone in favor of the proposed policy and bylaw changes for submission for public comment: 13-supported; 0-opposed; and, 0-abstained.

Supporting Evidence and Modeling:

On December 31, 2011, there were 217 registrations and 212 candidates on the pancreas islet waiting list. The number of pancreas islet registrations increased from 182 registrations in 1999 to 334 registrations in 2002 and remained relatively stable through 2005. Between 2005 and 2008, however, registrations decreased to 190 and have since increased only slightly. As expected, trends in the number of pancreas islet candidates followed the same pattern as that of registrations, with very few candidates listed at multiple hospitals.

In 2011, there were 61 deceased donor pancreata reported to the OPTN with a disposition code of “Islet Cells Transplanted.” There were 87 removals from the waiting list in 2011 for pancreas islet infusions reported to the OPTN. 70 recipients were removed from the waiting list for pancreas islet transplants. The discrepancy in these numbers is caused by the removals for recipients removed more than once; 15 recipients were removed twice and one recipient was removed thrice for pancreas islet transplants. The difference in the number of donors reporting that islet cells were transplanted and the number of recipients removed from the waiting list for an islet cell transplant shows that the OPTN does not have a precise count of the number of islet transplants. However, both numbers show that the number of islet transplants annually is likely less than 100.

As of July, 2012, there are currently 21 approved pancreas islet programs.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

This proposal affects islet recipients because it shows which islet recipients have received islets from deceased donors. This information would be particularly important if an OPO needed to notify recipients of a potential disease transmission or other patient safety issue. There were approximately 60-80 islet infusions in 2011. This proposal would allow the OPTN Contractor to have a more accurate count of the impact of islet policy changes.
Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposal addresses the OPTN Strategic Plan goal to promote transplant patient safety. By having accurate and timely reporting of every islet infusion, it will be easier for both members and the OPTN Contractor’s patient safety and disease transmission staff to notify the islet program and recipient of any potential patient safety or disease transmission events.

This proposal also addresses the OPTN Strategic Plan Goal of promoting efficient management of the OPTN. First, it aligns the process for reporting islet transplants with the process and timeframes for reporting all other organ transplants. Additionally, this proposal removes outdated language in the bylaws about requiring islet logs. Islet programs cannot comply with those requirements because there is no mechanism for collecting the logs. That situation creates confusion and inefficiencies for both Members and the OPTN Contractor’s staff when Transplant Programs try to determine how to comply with OPTN requirements.

Plan for Evaluating the Proposal:

The Committee will review the number of islet transplants annually and compare it to the number of deceased donors when the disposition of the pancreas is “islet cells transplanted.” The Committee expects each donor ID with the “islet cells transplanted” disposition code to match to an islet candidate who has been removed from the waiting list with a removal code of “transplanted.” Without the requirement to report every islet infusion, that comparison cannot be done.

The Committee asserts that the number of islet donors and islet recipients should be the same. If the numbers are not the same, then this proposed policy and bylaw changes may not have achieved its goal of accurate and timely reporting of every islet infusion. The Committee will then investigate whether there is a policy compliance issue or whether it needs to pursue an alternate solution.

Additional Data Collection:

This proposed policy and bylaw change does not require additional data collection, but does require islet Transplant Programs to report data on islet infusions on a different time frame. Transplant Programs already collect these data, and the Unet℠ system already has an automated mechanism for reporting islet infusions. However, Transplant Programs do not use this automated mechanism consistently.

Expected Implementation Plan:

The Board will consider this proposal in June, 2013. If approved by the Board, the proposed policy and bylaw language will be effective on September 1, 2013. (The proposal will not require programming in UNet℠.)

If approved, islet Transplant Programs must remove islet recipients from the waiting list within 24 hours of each islet infusion instead of 24 hours of the recipient’s third islet infusion. Policy 3.2.8 (Patient Notification) requires that Transplant Hospitals notify patients in writing within 10 business days of the patient’s registration on the waiting list. If this proposal is a change in practice for the islet program, then the program should review its patient notification protocol to make sure that it is addressing cases when an islet recipient receives an islet transplant and is immediately re-registered for another infusion.
Islet programs no longer will be required to submit cumulative islet logs reporting each islet infusion and outcomes.
Compliance Monitoring:

The proposed policy changes would not affect the OPTN Contractor’s monitoring.

Policy and Bylaw Proposal

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

3.8.7 Islet Allocation Protocol

[There are no policy changes preceding Policy 3.8.7.2.]

3.8.7.2 Accrual of Waiting Time.

A candidate will begin to accrue islet waiting time when the candidate is registered on the waiting list. Candidates accrue waiting time while registered at an active or inactive status.

An islet candidate will retain waiting time through three registrations at the registering center, including the waiting time from the previous registrations and any intervening time. After a candidate has received a series of three islet infusions at the registering hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions.

A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and

- until the candidate has received a maximum of three islet infusions.

Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

[There are no further changes in Policy 3.8.7.2. There are no changes in Policy 3.8.7.3.]

3.8.7.4 Process for Re-Allocating Islets. If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and

- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.
The transplant center must maintain this documentation and submit it upon request. Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,

- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers, and

- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,

- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

3.8.7.5 **Removal from the Pancreas Islet Waiting List.**
The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving each his/her third islet infusion.
G.4  Requirements for Designated Pancreatic Islet Transplant Programs

All Pancreatic Islet Transplant Programs must meet the following criteria:

1. All of the requirements of a Designated Pancreas Transplant Program as defined in the sections above or meet the criteria for an exception as detailed in Section G.4.E: Programs Not Located at an Approved Pancreas Transplant Program below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

A. Reporting

The Program must submit data to the OPTN Contractor for all donors, potential transplant recipients, and actual transplant recipients using the required forms.

Pending development of standardized data forms for pancreatic islet transplantation, the Program must maintain patient logs and provide them to the OPTN Contractor every 6 months. The patient logs must be cumulative and must include for each transplant performed:

1. The patient name
2. Social security number
3. Date of birth
4. Donor ID
5. Patient status (alive or dead)
6. Whether the pancreas was allocated for islet or whole organ transplantation

For each pancreas allocated to the Program for islet transplantation, the Program must report to the OPTN Contractor if the islets were used for transplantation. If the islets were not used in transplantation, the Program must report the reason and disposal method, together with other information requested on the Pancreatic Islet Donor Form.

AB. Transplant Facilities

The Program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The Program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

BC. Expert Medical Personnel

The program must have a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon. It is further recommended that the Program have on site or adequate access to:
1. A board-certified endocrinologist
2. A physician, administrator, or technician with experience in compliance with FDA regulations
3. A laboratory-based researcher with experience in pancreatic islet isolation and transplantation

Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.

CD. Islet Isolation

Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and the facility.

DE. Programs Not Located at an Approved Pancreas Transplant Program

A Program that meets all requirements for a Designated Pancreatic Islet Transplant Program but is not located at a hospital approved as a Designated Pancreas Transplant Program may qualify as a Pancreatic Islet Transplant Program if the following additional criteria are met:

1. The Program demonstrates a documented affiliation with a Designated Pancreas Transplant Program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.
2. The Program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.
3. The Program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. An informal discussion with the MPSC is also required.
OPTN Bylaws

Article I: Membership

1.2 Transplant Hospital Members

D. Registration Fees

Transplant hospital members are responsible for the payment of an OPTN Registration Fee for each transplant candidate listed by that member on the waiting list database maintained by the OPTN Contractor. The OPTN Registration Fee is proposed by the Board of Directors and determined by the Secretary of HHS.

An additional registration fee will be due for a transplant candidate if:

- A candidate is given an inactive status or removed from the waiting list without receiving a transplant and is not placed back on the list within the 90-day grace period.
- A recipient has received a transplant but is put back on the waiting list for another transplant. However, no additional registration fee will be due for an islet candidate who is removed and, if the option to re-register is offered during the removal process, immediately re-registered for an islet infusion.
- A candidate is transferred to a transplant hospital outside the original OPO Donation Service Area. A new registration fee must be paid by the receiving hospital.
- The potential recipient is listed at multiple transplant hospitals. A registration fee must be paid by each transplant hospital that places the candidate on the waiting list.

Members who list candidates needing more than one organ (for example, kidney and pancreas) are only charged one registration fee.
At-a-Glance

- **Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation**

- **Affected Bylaw**: Appendix J (Membership and Personnel Requirements for Combined Heart and Lung Program)

**Thoracic Organ Transplantation Committee and the Membership and Professional Standards Committee (MPSC)**

- The proposed change removes an OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

  A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to transplant organs for which the transplant hospital has already been approved. Aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. The combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

- **Affected Groups**
  - Transplant Administrators
  - Transplant Physicians/Surgeons
  - Transplant Program Directors
  - General Public

- **Number of Potential Candidates Affected**
  - There is no known impact to heart-lung transplant candidates.

- **Compliance with OPTN Strategic Goals and Final Rule**
  - The proposed bylaw proposal promotes the efficient management of the OPTN by reducing programming and application processing, and aligning the combined heart lung transplant program approval requirements with other multi-organ transplant programs.

- **Specific Requests for Comment**
  - None.
Proposal to Remove the OPTN and UNOS Bylaws for the Combined Heart-Lung Transplant Program Designation

Affected Bylaw: Appendix J (Membership and Personnel Requirements for Combined Heart and Lung Program)

Thoracic Organ Transplantation Committee and the Membership and Professional Standards Committee (MPSC)

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The proposed change removes an OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to transplant organs for which the transplant hospital has already been approved. Aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. The combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

Background and Significance of the Proposal:

In its effort to upgrade its computer system, the OPTN Contractor identified an opportunity to streamline the process for a transplant hospital to obtain a single combined heart-lung transplant program designation.

In order to perform a heart-lung transplant, current bylaws require the transplant hospital to not only have an approved heart transplant program and an approved lung transplant program, but it must also have an approved combined heart-lung transplant program. In contrast, to perform a kidney-pancreas transplant, the OPTN bylaws only require a transplant hospital to concurrently have both an approved kidney transplant program and an approved pancreas transplant program.

Current OPTN bylaws require the transplant hospital to submit the names of a primary transplant surgeon and physician for the heart-lung program. Typically, the names reported to the OPTN Contractor are identical to those that qualified the transplant hospital for approval of its individual heart and lung transplant programs. Other than submitting key heart-lung personnel applicant information, there are no additional requirements for transplant hospitals to qualify for the single combined heart-lung transplant program designation.

The removal of the combined heart-lung transplant program designation in the bylaws would reduce the paperwork that a transplant hospital would have to complete, as long as the transplant hospital is already approved for both heart and lung transplant programs individually. The administrative burden on the OPTN contractor would also be reduced, as the OPTN Contractor tracks program and outcome information for combined heart-lung transplant programs separately in its database.
The initial indication from the Centers for Medicare and Medicaid Services (CMS) is that the proposed bylaw change is reasonable, and one which the CMS can incorporate into its transplant program designation regulations.

The MPSC and the Thoracic Committee voted in favor of the proposal and submitting the bylaw changes for public comment. The MPSC voted in July, 2012 as follows: 32-supported; 1-opposed; and, 2-abstained. The Thoracic Committee voted in July, 2012 as follows: 19-supported; 0-opposed; and, 0-abstained.

**Supporting Evidence and/or Modeling:**

In assessing whether to retain the combined heart-lung transplant program designation, it was agreed that the OPTN bylaws should be amended so that transplant hospitals are not unnecessarily burdened to submit paperwork for approval of a separate program specifically to perform combined organ transplants when approval has already been obtained for heart and lung transplant programs individually.

Administrative costs for operating the OPTN will also be removed. Currently, it takes 50 hours of staff and MPSC resource commitment to process and approve each heart-lung program. The MPSC and Thoracic Committee expect that following implementation, the MPSC would spend zero hours annually processing and monitoring combined heart-lung programs. The MPSC and Thoracic Committee also expect to find IT resource savings because additional organ transplant programs will not need to be programmed or maintained in the Chrysalis system. This approach would also remove costs for coding each of the combined transplant program approvals, and help to ensure currency and accuracy of transplant program data.

**Expected Impact on Living Donors or Living Donation:**

None

**Expected Impact on Specific Patient Populations:**

There is no known impact to heart-lung transplant candidates.

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

The proposed bylaw proposal promotes the efficient management of the OPTN by reducing programming and application processing, and aligning the combined heart-lung transplant program approval requirements with other multi-organ transplant programs.

**Plan for Evaluating the Proposal:**

The MPSC and Thoracic Committee will evaluate whether the removal of the combined heart-lung transplant program designation creates efficiency in OPTN operations. The MPSC will compare the hours spent processing and monitoring combined heart-lung transplant programs in the three years prior to the removal of this requirement, to the hours spent processing and monitoring combined heart-lung transplant programs in each year following implementation of the removal.
Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The OPTN/UNOS Board of Directors will consider this proposal in June, 2013. If approved by the OPTN/UNOS Board of Directors, the OPTN Contractor will implement the bylaw change pending programming. Upon approval, transplant programs will no longer be required to submit a program application or key personnel changes for combined heart-lung programs.

Compliance Monitoring:

This proposal will not affect monitoring of heart and lung programs. However, UNOS will no longer review applications for nor designate heart-lung programs.
Bylaw Proposal:

The modifications to Appendix J, Section D.9 appear below with deleted language marked with strikethroughs.

Appendix J:
Membership and Personnel Requirements for Joint Heart and Lung Programs

A designated heart and lung transplant program must have current approval as a designated heart transplant program and a designated lung transplant program as described in:

- Appendix H: Membership and Personnel Requirements for Heart Transplant Programs
- Appendix I: Membership and Personnel Requirements for Lung Transplant Programs

Designated heart and lung transplant programs must also meet general membership requirements, which are described in Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs of these Bylaws.

For more information on the application and review process, see Appendix A: Membership Application and Review of these Bylaws.

J.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician

A heart and lung transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below in Sections J.2 and J.3. The primary surgeon and physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see Appendix D, Section D.5.B: Surgeon and Physician Coverage of these Bylaws.

J.2 Primary Heart and Lung Transplant Surgeon Requirements

A designated heart and lung transplant program must have on site a qualified transplant surgeon who meets the requirements for primary heart transplant surgeon or primary lung transplant surgeon as defined in these Bylaws.
J.3—Primary Heart and Lung Transplant Physician

A designated heart and lung transplant program must have on site a qualified transplant physician who meets the requirements for primary heart transplant physician or primary lung transplant physician as defined in these Bylaws.
Proposal to Change the Composition of the OPTN Finance Committee

Affected Bylaws: OPTN Article VII (Permanent Standing Committees); Article 7.6 (Conflicts of Interest); and proposed Article 7.6 (Finance Committee)

Executive Committee

To improve the efficient management of the OPTN, this proposal recommends changing the composition of the OPTN Finance Committee so that it consists of members of the OPTN Board of Directors. Currently, the OPTN Finance Committee is a permanent standing committee with regional and at-large appointments, and it reports to the OPTN Board of Directors. For most organizations, financial governance begins with a finance committee that resides at the board level.

Affected Groups
This proposal recommends that the OPTN Finance Committee solely consist of members from the OPTN Board of Directors. All professionals in the transplant community who have an interest in serving the OPTN Finance Committee would be indirectly affected by this change.

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

Number of Potential Candidates Affected
The change recommended in this proposal will not affect any transplant candidates. This is an organizational change which aims to improve the efficient management of the OPTN so that all involved in the organ transplant process may be better served.

Compliance with OPTN Strategic Goals and Final Rule
The changes recommended in this proposal align with the key goal of the OPTN Strategic Plan to promote the efficient management of the OPTN.
Proposal to Change the Composition of the OPTN Finance Committee

Affected Bylaws:  OPTN Article VII (Permanent Standing Committees); Article 7.6 (Conflicts of Interest); and proposed Article 7.6 (Finance Committee)

Executive Committee

Public Comment Response Period:  September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

To improve the efficient management of the OPTN, this proposal recommends changing the composition of the OPTN Finance Committee so that it is consists of members of the OPTN Board of Directors. Currently, the OPTN Finance Committee is a permanent standing committee with regional and at-large appointments, and it reports to the OPTN Board of Directors. For most organizations, financial governance begins with a finance committee that resides at the board level.

Background and Significance of the Proposal:

At its June 2012 meeting, the OPTN Board of Directors (the Board) developed and adopted a strategic plan for the OPTN. The strategic plan consists of six key goals, one of which is to promote the efficient management of the OPTN. Financial governance is a major component in the efficient management of the OPTN. To improve the OPTN’s financial governance efficiency, it is believed that the current structure of the OPTN Finance Committee should be changed.

Currently, the OPTN Finance Committee is a constituent committee with regional and at-large appointments, and it reports to the Board. For most organizations, financial governance begins with a finance committee that resides at the board level. This proposal recommends changing the composition of the OPTN Finance Committee so that it consists of members of the Board. This change does not necessarily eliminate regional and at-large representation on the Finance Committee. Rather, the proposal only recommends changing the Finance Committee from being a constituent committee that reports to the Board, to one that is an arm of the Board, and exclusively composed of its members.

With this change, the OPTN’s operational and financial decision making processes are expected to be better aligned. Currently, the Board receives biannual reports from the Finance Committee during its summer and winter meeting. As such, it is difficult to align actions of the Finance Committee and the Board, as they are distinct groups with minimal overlap. With the proposed changes, Board members that are on the Finance Committee will be more informed, and therefore better suited to interject financial considerations during Board meeting discussions.

Expected Impact on Living Donors or Living Donation:

This proposal does not impact living donors or living donation. This is an organizational change which aims to improve the efficient management of the OPTN so that all involved in the organ transplant process, including living donors and recipients of live donor organs, may be better served.
Expected Impact on Specific Patient Populations:

The change recommended in this proposal will not affect any transplant candidates. This is an organizational change which aims to improve the efficient management of the OPTN so that all involved in the organ transplant process may be better served.

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

Changing the composition of the Finance Committee advances the OPTN Strategic Plan’s key goal to “Promote the efficient management of the OPTN.” As the impetus for this change is rooted solely in the advancement of this goal, the previous sections of this proposal have explained how these changes will contribute to it.

Plan for Evaluating the Proposal:

Not applicable

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The changes recommended in this proposal will require approval by the Board, as well as HRSA. If these changes are adopted, members should make themselves aware of the new structure for the OPTN Finance Committee. Operationally, members do not need to do anything to prepare for this change.

Compliance Monitoring:

Not applicable.

Bylaw Proposal:

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

Article VII: Permanent Standing Committees

The OPTN will have the following permanent standing Committees:

- Ethics
- Finance
- Histocompatibility
- Kidney Transplantation
- Liver and Intestinal Organ Transplantation
- Living Donor
The Committees are advisory to the Board of Directors, which makes the final decisions of the OPTN. The standing Committees will provide initial review and analysis of proposed policies and initiatives based on their collective expertise and unique perspectives, and present their recommendations to the Board of Directors.

Committees may also be advisory to each other when Committee interest and expertise overlap. When Committees evaluate proposals jointly, they should present to the Board of Directors either a common recommendation or a report that summarizes the continued disagreement.

Committees may have additional responsibilities as defined by the OPTN Bylaws and Policies. Committees’ role in developing policies and standards is further defined in Article XI: Adoption of Policies of these Bylaws.

7.6 Finance Committee

In addition to the permanent standing committees listed above, the OPTN will have a Finance Committee to assist in the governance of the OPTN.

The Finance Committee will report to the Board. The Finance Committee will have members, composition, terms, and duties, as may be determined by the President in consultation with the Board of Directors. The President may appoint any number of non-voting Advisors to the Finance Committees subject to approval by the Board of Directors for terms the President may deem appropriate.

7.6.7 Conflicts of Interest

All OPTN standing Committee members must avoid conflicts of interest and the appearance of conflicts of interest. Committee members will be held to the standard for conflicts of interest as described in Article 2.7: Conflicts of Interest of these Bylaws.
Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity

**Affected/Proposed Bylaw:** Appendix D, Section D.9 (Review of Transplant Program Functional Activity) and Appendix K, Section 1 (Transplant Program Inactivity)

**Membership and Professional Standards Committee (MPSC)**

The purpose of this proposal is to better define the notification requirements for periods of functional inactivity. Currently, the Bylaws do not clearly outline the actions a Member must take when it becomes functionally inactive. This Bylaw proposal clarifies the current notification requirements for functional inactivity by including specific requirements for notification of functional inactivity, including waiting list inactivation in UNet™. These modifications also specify what a member must do in terms of notifying patients when a program voluntarily ceases performing a specific type of transplant.

**Affected Groups**
- Transplant Program Directors
- Transplant Administrators
- Transplant Physicians/Surgeons
- Transplant Data Coordinators
- Organ Recipients
- Organ Candidates
- Living Donors

**Number of Potential Candidates Affected**
Functional inactivity affects both potential candidates and candidates. During 2011, approximately 154,000 candidates were registered on a waiting list for at least one day.

Over the course of 2011, 12 transplant programs met notification thresholds for an inactive waiting list, which affected approximately 1,000 candidates.

Additionally, four programs ceased performing either age-specific or donor-specific transplants during 2011, which affected approximately 2,900 candidates.

**Compliance with OPTN Strategic Goals and Final Rule**
This proposal addresses the strategic plan goal of promoting the efficient management of the OPTN. This proposal clarifies existing bylaw language regarding functional inactivity and the MPSC’s review of transplant program performance. Member responsibilities and expectations are clearly defined in the proposal and will result in improved interpretation of and compliance with Bylaw requirements.
• **Specific Requests for Comment**
  Please do not limit your response to the questions outlined below.

  For Program Component Cessation:
  o This proposal uses the phrase ‘affected patients’ instead of listing which patients must be notified (e.g. Should adult patients be notified of pediatric cessation; should candidates waiting for a living donor and potential living donors be notified of deceased component cessation). Is this language clear enough for members to understand which patients must be notified?
  o Should adult candidates be notified of the cessation of a pediatric component of a transplant program? Similarly, should pediatric patients be notified of the cessation of an adult component of a transplant program?
  o Should transplant recipients be notified of the cessation of living donor, deceased donor, or age-specific transplantation program components? Similarly, should post-donation living donors be notified of the cessation of living donor, deceased donor, or age-specific transplantation program components?
  o Should there be different timelines for patient notification for living versus deceased donor program components?
Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity

Affected/Proposed Policy: Appendix D, Section D.9 (Review of Transplant Program Functional Activity) and Appendix K, Section 1 (Transplant Program Inactivity)

Membership and Professional Standards Committee (MPSC)

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The purpose of this proposal is to better define the notification requirements for periods of functional inactivity. Currently, the Bylaws do not clearly outline the actions a Member must take when it becomes functionally inactive. This Bylaw proposal clarifies the current notification requirements for functional inactivity by including specific requirements for notification of functional inactivity, including waiting list inactivation in UNet™. These modifications also specify what a member must do in terms of notifying patients when a program voluntarily ceases performing a specific type of transplant.

Background and Significance of the Proposal:

The Bylaws currently define functional inactivity as:

1. The inability to serve potential candidates, candidates, or recipients for a period of 15 or more consecutive days.
2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.
3. The failure to perform a transplant during the periods defined in the table below:

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Inactive Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney, Liver or Heart</td>
<td>3 consecutive months</td>
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<td>6 consecutive months</td>
</tr>
<tr>
<td>Stand-alone pediatric transplant programs</td>
<td>12 consecutive months</td>
</tr>
</tbody>
</table>

The MPSC currently monitors functional inactivity, including periods of wait list inactivation. The purpose of the original Bylaw was to ensure that candidates would be better informed of periods when organ offers would not be made to the transplant program on behalf of the candidates. As the MPSC has continued to monitor these programs, there have been questions from both the transplant programs and MPSC members regarding specific content requirements in the patient notifications and the timing of these notifications.

The OPTN currently does not have separate approval statuses for a subsection or component of programs (e.g. pediatric and adult or living donor and deceased). Since programs are approved to perform organ-specific transplants, regardless of the patient age or donor type, a program cannot inactivate its membership status if it decides to cease performing transplants for a component. There are currently no expectations outlined for programs that voluntarily cease performing a specific type of...
transplant. Even though programs cease performing a certain type of transplant and do not inactivate their program status, certain patients may be impacted by this decision and should receive notification which provides detailed information and options.

A focus group comprised of MPSC, Transplant Administrators Committee, and Patient Affairs Committee members met to discuss modifications to the Bylaw requirements for patient notification of cessation of components of a program and of inactivation of waiting lists. This work group reviewed existing Bylaw language and observed that there were no specific notification content or timing requirements for either periods of waiting list inactivation or voluntary cessation of a program component. The proposed bylaw language will provide clear expectations of notification responsibilities for transplant programs and provide the MPSC with more guidance for monitoring functional inactivity.

While these modifications are an improvement, transplant programs may feel additional burden since they must notify candidates during periods of cessation of a program component and within specific time periods for waiting list inactivation. This added burden may be in the form of increased patient questions and calls regarding correspondence from the transplant program, or an increased financial burden related to the costs of providing written notification to all candidates and affected patients. Additionally, transplant programs may be required to respond to MPSC inquiries regarding waiting list inactivation and cessation.

**Details of the Proposal:**

This proposal will require transplant programs to notify patients when one of more of the following conditions are met: 15 or more consecutive or 28 or more cumulative days of waiting list inactivation.

Programs must include the following information in the patient notification letters:

- The reason for the inactivity
- The expected length of time that the waiting list will be inactive
- The explanation that during the period of inactivity, organs cannot be accepted on the candidate’s behalf at this transplant program
- The options available to the candidates during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
- How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
- A copy of the Patient Information Letter
- If written notice is required because a Transplant Program exceeded the inactive waiting list threshold due to *cumulative* periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation

Programs must provide notice within the periods defined in the table below:

<table>
<thead>
<tr>
<th>For… Periods of waiting list inactivation scheduled at least 30 days in advance</th>
<th>Written Notice Must be Provided… 30 days before inactivity begins.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periods of waiting list inactivation scheduled less than 30 days in advance</td>
<td>No more than 7 days following the initial date of waiting list inactivation.</td>
</tr>
</tbody>
</table>
Any periods of waiting list inactivation related to a cumulative period of inactivation

<table>
<thead>
<tr>
<th>Center A</th>
<th>Start Date</th>
<th>Consecutive # of Days Inactive</th>
<th># of Days WL inactive for Review Period</th>
<th>Running total: Cumulative # of days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instance 1 of WL Inact</td>
<td>1/10/11</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Instance 2 of WL Inact</td>
<td>3/15/11</td>
<td>7</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Instance 3 of WL Inact</td>
<td>6/27/11</td>
<td>7</td>
<td>7</td>
<td>17</td>
</tr>
<tr>
<td>Instance 4 of WL Inact</td>
<td>8/20/11</td>
<td>4</td>
<td>4</td>
<td>21</td>
</tr>
<tr>
<td>Instance 5 of WL Inact</td>
<td>11/22/11</td>
<td>13</td>
<td>13</td>
<td>34</td>
</tr>
<tr>
<td>Instance 6 of WL Inact</td>
<td>12/22/11</td>
<td>7</td>
<td>7</td>
<td>41</td>
</tr>
<tr>
<td>Total # of Cumulative Days WL Inactivated in Period 1</td>
<td></td>
<td></td>
<td></td>
<td>41</td>
</tr>
</tbody>
</table>

Within Instance 5, the program reaches the 28 day threshold and must notify patients no later than 12/5/11 (7 days following Day 13) and must also notify for any subsequent periods when the threshold is surpassed; therefore in Instance 6, the program must again notify patients no later than 12/29/11 (7 days following Day 7).

This proposal would also require transplant programs that cease a component of the program to:
- Notify all patients affected by the cessation at least 30 days prior to, but no later than 7 days after cessation of a program component. Notification letters must include:
  - The reason for cessation
  - The explanation that organs cannot be accepted on the candidate’s behalf during period of cessation
  - The options to transfer to another program
  - The phone number for the transplant program’s administrative office to assist with transfer to another program

**Supporting Evidence and/or Modeling:**

UNOS staff routinely receive questions from transplant programs regarding patient notifications of waiting list inactivation and program component cessation; therefore, the MPSC wanted to add clarity to the existing Bylaws.
Expected Impact on Living Donors or Living Donation:

This proposal impacts living donation in situations where the transplant program has ceased performing living donor transplants. This proposal would require that transplant programs inform all affected parties of the decision for cessation of program components and available options for living donors and potential living donors.

Expected Impact on Specific Patient Populations:

This proposal impacts pediatric or adult patients in situations where the program has ceased performing pediatric or adult transplants. This proposal would require that transplant programs inform all affected parties of the decision for cessation of a program component and available options.

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

This proposal addresses the strategic plan goal of promoting the efficient management of the OPTN. This proposal clarifies existing bylaw language regarding functional inactivity and the MPSC's review of transplant program performance. Member responsibilities and expectations are clearly defined in the proposal and will result in improved interpretation of and compliance with Bylaw requirements.

Plan for Evaluating the Proposal:

The MPSC will continue to monitor the frequency of waiting list inactivation and trends. The MPSC will evaluate the responses to its inquiries to active programs with inactive waiting lists according to the proposed modifications, both those greater than 14 consecutive days and 28 or more cumulative days. The MPSC will also evaluate notifications to patients affected by the cessation of a portion of a program.

Additional Data Collection:

This bylaw proposal should not result in additional data collection.

Expected Implementation Plan:

This proposal will be considered by the Board of Directors in June 2013. If approved, the changes will be effective September 1, 2013.

The current Bylaws require transplant programs to notify candidates in writing of periods when their waiting list default is set to inactive for 15 or more consecutive days or 28 or more cumulative days in a 365 day period. If this proposal if approved, these notifications must contain all of the required elements and must be sent within the timeframes outlined in the proposal details section above.

There are currently no requirements for notification of voluntary cessation of a transplant program subsection or component. If this proposal is approved, transplant programs must notify the OPTN in writing and send a representative copy of the notification and a list of all patients that received the notification. Notifications must contain all of the required elements and must be sent within the timeframes outlined in the proposal details section above.
The MPSC will continue to monitor transplant program compliance with requirements contained in the proposal.

**Compliance Monitoring:**

Concerning waiting list inactivation, the MPSC Performance Analysis and Improvement Subcommittee will continue to monitor compliance with bylaw requirements as part of its existing review of functional inactivity. UNOS will review a list of all Members that ever inactivated their waiting list for one or more of the following time periods: 15 or more consecutive days or 28 or more cumulative days over a rolling 365 day period. (This is an existing report.) UNOS will then send a letter to these programs and request confirmation that candidates were notified of the period(s) of waiting list inactivation, in compliance with the proposed content and timing requirements.

The MPSC will also monitor programs that voluntarily cease performing a specific type of transplant. UNOS will request confirmation that the affected groups, outlined in the proposed language, were notified of the cessation, in compliance with the proposed requirements.

UNOS already works with Members that voluntarily inactivate a transplant program or cease performing a specific type of transplant, and help these transplant programs with the transition. If a Member is found to be noncompliant with the Bylaw, the Member will be referred to the MPSC. The Committee will follow its normal process for investigation and may take action as defined in Appendix L of the Bylaws.
Policy or Bylaw Proposal:

The MPSC voted on December 7, 2011, to distribute the following proposed modifications to the Bylaws for public comment, by a vote of 23 For, 8 Against, 0 Abstentions.

The Modifications to Appendix D, Section D.9 and Appendix K, Section 1 appear below with new language underlined and deleted language marked with strikethroughs.

Appendix D:
Membership Requirements for Transplant Hospitals and Transplant Program

No changes to Sections D.1 through D.10.

D.9 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active. Transplant program functional activity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC. For purposes of these Bylaws, functional inactivity is defined as any of the following:

1. The inability to serve potential candidates, candidates, or recipients, potential living donors, or living donors for a period of 15 or more consecutive days.
2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over any 365 consecutive day period.
3. The failure to perform a transplant during the periods defined in the table below:

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</table>

Given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements for functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

B. Requirements of Functional Inactivity

A transplant program must provide written notice to candidates if it does either or both of the following:

1. Inactivates its waiting list or is unable to perform transplants for 15 or more consecutive days.
2. Inactivates its waiting list or is unable to perform transplants for 28 or more cumulative days over any 365 consecutive day period.

A Transplant Program must provide written notice each time it reaches either of the inactive waiting list thresholds listed above. Written notice must include all of the following:
1. The reason for the inactivity
2. The expected length of time that the waiting list will be inactive
3. The explanation that during the period of inactivity, organs cannot be accepted on the candidate’s behalf at this transplant program
4. The options available to the candidates during this period, including multiple listing or transferring of accrued waiting time to another Transplant Hospital
5. How the candidates will be notified when the waiting list is reactivated or if the expected length of inactivation is extended
6. A copy of the UNOS Patient Information Letter

**Note:** If written notice is required because a Transplant Program exceeded the inactive waiting list threshold due to *cumulative* periods of inactivation, then the written notice must also include the dates of each instance of waiting list inactivation.

Written notice must be provided within the periods defined in the table below:

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<td>No more than 7 days following the initial date of waiting list inactivation.</td>
</tr>
<tr>
<td>Any periods of waiting list inactivation related to a cumulative period of inactivation</td>
<td>No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.</td>
</tr>
</tbody>
</table>

Copies of all written notifications must be retained and be provided to the OPTN Contractor on request.

**C. Review of Member Functional Inactivity**

The MPSC may also require, at its discretion, that the member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC.

The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to 12 months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than 12 months, the member should relinquish designated transplant program status as required in these Bylaws.
The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program’s functional inactivity. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program’s inactivity.

No Changes to Sections K.2 through K.7.

Appendix K:
Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

K.1 Transplant Program Inactivity
Transplant programs must remain active in transplantation to maintain membership in the OPTN. There are two types of member inactivity:

1. Short-term Inactivity
2. Long-term Inactivity

A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- The inability to meet functional activity requirements.
- Temporarily lacking required physician or surgeon coverage.
- A substantial change in operations that requires an interruption in transplantation.

For more information about the functional activity requirements for transplant programs, see Appendix D, Section D.9: Review of Transplant Program Functional Activity of these Bylaws.

A. Program Component Cessation

Programs that cease performing a specific type of transplant (e.g., the living donor component of a transplant program, or cessation of only pediatric or only adult transplants in a transplant program that performs both), must notify every patient affected by the cessation, including:

- Potential candidates, including those currently in the referral or evaluation process
- All candidates registered on the waiting list
- Potential living donors, including those currently in the referral process, in the evaluation process, or awaiting donation

For more information about the notification content and timing requirements, see Appendix K, Sections K.3-4: of these Bylaws.
**At-a-Glance**

- **Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions**

- **Affected/Proposed Policy:** Policies 7.1.6 and 7.1.7 (Data Submission Requirements)

- **Organ Procurement Organization (OPO) Committee**

  The proposed changes clarify the data collection definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs must classify a death as one of the following: Imminent Neurologic Death (“imminent”), Eligible Death (“eligible”), or neither “eligible” nor “imminent” (“neither”). The OPOs then report the “imminent” and “eligible” deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

  The changes proposed by the Committee eliminate multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as “eligible” and add a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of “imminent” to restrict it to those deaths that would most likely be classified as “eligible” had brain death been legally declared. This change could allow the combination of “eligible” and “imminent” deaths to mitigate the effect of the variation in brain death laws.

- **Affected Groups**
  - Directors of Organ Procurement
  - OPO Executive Directors
  - OPO Medical Directors
  - OPO Coordinators
  - PR/Public Education Staff

- **Number of Potential Candidates Affected**
  There is no immediate effect on candidates or the candidate pool. The Committee anticipates that with more accurate data reporting, OPOs will be able to improve their processes and better identify donor potential.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The changes support the goal to Promote the Efficient Management of the OPTN by trying to accurately capture the eligible and imminent deaths. These data will be used for better performance modeling.

- **Please Note**
  Please note that the definitions are “reporting” definitions only. They are NOT intended to be inclusive of all actual donors; therefore, they should NOT be used for screening donors or affect allocation or acceptance of organs. These criteria are not used to rule out potential organ donors and do not exclude an OPO from pursuing a donor candidate that is not classified as an Eligible Death.
Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions

Affected/Proposed Policy: Policies 7.1.6 and 7.1.7 (Data Submission Requirements)

Organ Procurement Organization (OPO) Committee

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The proposed changes clarify the definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs must classify a death as one of the following: Imminent Neurologic Death (“imminent”), Eligible Death (“eligible”), or neither “eligible” nor “imminent” (“neither”). The OPOs then report the “imminent” and “eligible” (I &E) deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The changes proposed by the Committee eliminate multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as “eligible”, and add a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of “imminent” to restrict it to those deaths that would most likely be classified as “eligible” had brain death been legally declared. This change could allow the combination of “eligible” and “imminent” deaths to mitigate the effect of the variation in brain death laws.

Background and Significance of the Proposal:

Please note that the imminent and eligible definitions are “reporting” definitions only. They are not intended to be inclusive of all actual donors; therefore, they should not be used for screening donors or affect allocation or acceptance of organs. These criteria are not used to rule out potential organ donors and do not exclude an OPO from pursuing a donor candidate that is not classified as an Eligible Death.

The OPTN Contractor began collecting patient level data for all I & E deaths on January 1, 2008 in hopes that OPOs would have better performance modeling and would identify potential donors that might have otherwise been missed. The committee wrote I & E definitions and the Board approved them.

At that time, the OPO Committee sponsored two I & E training sessions to introduce the information to the community. Additionally, the AOPO Quality Council created a guidance document to help OPOs report these data accurately [Charlie Alexander, former chair of the OPO Committee provided oversight].

In spite of these efforts, OPOs have inconsistently reported these data. Because OPOs interpret reporting definitions differently (Policy 7.1), and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The eligible death definition contains a list of exclusionary criteria. A frequently misinterpreted criterion relates to MSOF defined as “the failure of 3 or more organ systems.” Some OPOs report an organ as a failed system if the organ is functioning but has some history of disease or surgery. In other words, a
heart which had undergone bypass surgery might be listed as a failed system, when in reality it is a functioning organ or system. Although this heart might not be considered an acceptable organ for transplant, it is not an organ in failure. The inconsistent way OPOs apply these definitions results in data that are not useful for interpretation or process improvement. Additionally, OPOs often pursue a single organ (and sometimes multiple organs) from donors that are considered “non-eligible” based on the definitions. In 2010, there were 589 donors that resulted in at least one organ recovered for transplant that did not meet the eligible death definition, thus resulting in inaccurate I & E data.

The Committee agreed that instead of using the number of failed systems to exclude a donor, it might be best to use the concept of “the absence of any transplantable organ” or “the presence of transplantable organ(s).” As such, a donor with any functioning organ (kidney, liver, heart or lung) that may be appropriate for transplant will be potentially identified as either an imminent or an eligible donor regardless of MSOF. After much consideration, the Committee accepted the “rule in” concept as opposed to the “rule out” model and agreed that OPOs must consider factors that “rule in” donated organs.

A data review demonstrated large inconsistencies and variations in how OPOs reported data. In order to determine why OPOs had such different reporting results, the Committee leadership contacted those OPOs that were reporting no, low, or exceptionally high rates of imminent and eligible donors. They found that some OPOs were using their own definitions and not the definition found in policy, and others were interpreting the definition differently (for example, MSOF). The Committee also considered how staff turnover could affect data reporting.

Not only is there a need for OPOs to consistently apply death definitions when reporting data, the Committee agreed that it needed to take into account the differences in the death declaration process among hospitals throughout the US. These differences affect data reporting. For example, some states require two brain death exams while others only require one. For those requiring two, if there is no possibility of gaining authorization for donation, then there may not be an incentive to perform a second brain death exam. In this scenario, the OPO would not report this patient as eligible. Yet if the OPO was in a state that required only one brain death exam, it would likely report the patient as eligible. Even in states that only require one brain death exam, individual hospitals may require two exams which could lead to inconsistent data reporting.

Some of the fundamental concepts suggested by the Committee included:

- Remove the MSOF exclusion from the definition since it is inconsistently applied. In its place should be “rule out” criteria for each individual organ system. This would result in OPOs reporting a patient as imminent or eligible if they have one organ that is transplantable, as long as that person does not have any of the other exclusionary factors. This concept is simplistic and easier to apply. This would create an inclusionary type of system because if one organ passes through the list of rule out criteria, then the donor would still be included in assessment of the OPO’s “conversion” rate.

- In the definitions, the current listed age range is 0 – 70 years of age. Members commented that OPOs frequently have donors over the age of 70, so the the age limit was raised to 75 years of age. The lower age range for children should not be considered, however, a minimum weight should replace the age. Committee members agreed that size is a more appropriate consideration when evaluating the pediatric population and sought guidance from the Pediatric
Committee. Data was also analyzed regarding the donors over 70 to determine the effectiveness of the organs procured from that age group.

- The Committee did not reach a conclusion regarding the calculation of conversion rates, but suggested a tiered approach to performance evaluation:
  - The number of eligible deaths converted to donors;
  - Different ways of analyzing imminent deaths; and
  - A total conversion rate combining imminent and eligible deaths in the denominator to help understand the OPO’s potential.

- In defining I & E deaths, it might encourage accurate data collection to focus on individual organs, (i.e. heart, lung, liver and kidney).

The Committee accepted these fundamental concepts and formed two work groups to identify organ-specific exclusionary criteria for each organ system and make recommended changes based on these concepts. One group focused on identifying exclusionary criteria for organs above the diaphragm and the other on organs below the diaphragm.

According to the current definition, to classify a death as an eligible death, brain death must be declared, the patient must be between 0 and 70 years of age, and have none of the exclusionary conditions (i.e. active infections, malignancy) listed in the policy. To help guide the discussion, the Committee reviewed data regarding age, weight and BMI of all donors over the last 3 years. The data included the number of transplant donors and donor yield as age or weight increases. The same was done for donor BMI. The proposed criteria were based on data that determined where 99% of transplant donors fall.

The Committee considered organ-specific criteria prior to distributing the proposal for public comment in September 2011. The Committee did not include organ-specific criteria in that proposal; however, following the review of comments received during public comment the Committee agreed to add organ-specific criteria. Since there were significant changes from the original proposal the Committee agreed that it should be distributed for public comment in the fall of 2012.

The Committee discussed the criterion, “No candidates on the list/exhausted the list,” that appears on each organ specific list. After considering multiple alternatives, the members agreed that a death should not be reported as an imminent or eligible death when an OPO evaluates and/or recovers an organ and no one will accept it.

Prior to the release of the original proposal in September 2011, the Committee considered raising the age of the eligible donor but opted not to do so at that time. After reconsidering this following the public comment period the Committee raised the age from 70 to 75 years old or younger. The Committee used the “99th percentile rule” to determine the overall age cutoff as well as the age cutoff for the individual organ systems. This was determined by looking at the age of transplant donors over the last 4 years for all transplant donors and for each organ.

<table>
<thead>
<tr>
<th>Type of donor and 99th percentile of age (last 4 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Transplant Donors: 76</td>
</tr>
<tr>
<td>Kidney Transplant Donors: 70</td>
</tr>
<tr>
<td>Liver Transplant Donors: 77</td>
</tr>
</tbody>
</table>
Heart Transplant Donors:  58  
Lung Transplant Donors:  65

Collaboration:

The Committee sought input from each of the organ-specific committees and the Pediatric Transplantation Committee during the development of the original proposal.

Alternatives considered:

- The Committee considered whether clearly defining MSOF would sufficiently encourage better data reporting. However, as they investigated the issue, they realized that the MSOF definition did not fully describe a potential donor’s condition. As such, they eliminated MSOF as an exclusionary criterion and added much more detailed organ-specific information.

- The Committee considered using the number of failed systems to exclude a donor (MSOF), but opted to use the concept of “the absence of any transplantable organ” or “the presence of transplantable organ(s).” As such, a donor with any functioning organ that may be appropriate for transplant will be potentially identified as either an imminent or an eligible donor regardless of MSOF.

- After much consideration, the Committee accepted the “rule in” concept as opposed to the “rule out” model and agreed that OPOs must consider factors that “rule in” donated organs. As such, it developed a list of exclusionary conditions that was much more definitive than “organ system failure.”

- The Committee considered multiple criteria that were ultimately not included in the list. Some of the criteria that were considered included renal artery stenosis, Glomerular Filtration Rate < 80, hemophilia, and Troponin > 10. The Committee spent considerable time defining “exhausting the list” and considered many factors when doing so.

- Members also considered instances when a potential donor from whom no organs can be placed should not be considered an imminent or eligible death. There are situations when a potential donor meets the requirements for the eligible definition, is consented and managed as a donor, but cannot proceed to organ recovery. This situation could be caused by
  - if no one is willing to accept the organs,
  - if the donor is taken to the OR but organs are declined, or
  - if organs are recovered but not able to be transplanted.

- The Committee originally agreed to a minimum weight of 5 kg; however, the Pediatric Transplantation Committee considered a minimum weight of 3 kg be used. After discussion and based on the data analyzed, the Committee concluded that 5 kg should be used.

Strengths

The proposal more clearly defines the imminent & eligible death definitions for reporting data. It will provide a better guideline for how to report a death as imminent or eligible for more consistent data reporting and provide valuable data for process improvement and donor potential.
Weaknesses

These changes will require education/training for individuals who are responsible for reporting these data. Also, individual data recording systems may need to be modified which may incur a cost to the member.

Intended consequences include improved accuracy and consistency in data reporting that will be beneficial for process improvement and identification of donor potential.

Unintended consequences include:

- The possibility that OPOs will consider these as “absolute donor rule out” definitions rather than just “reporting” definitions. These definitions are not intended to say an OPO cannot recover organs from this donor.

- The comparison of “conversion” rates pre- and post- policy modification will be affected as it would be expected that improved accuracy of eligible death data reporting will result in some OPOs reporting more eligible deaths. This will affect conversion rate calculations. While this is noteworthy, it is not considered a negative as the true value of these data is in benchmarking OPO vs. OPO or OPO vs. national mean for like time periods. As all data submitted post implementation would be impacted, the effectiveness of benchmarking should be improved by having data that are more consistent.

Supporting Evidence and/or Modeling:

To help guide the discussion, the Committee reviewed data regarding age, weight and Body Mass Index (BMI) of all transplant donors over the last 3 years. The data included the number of transplant donors and donor yield as age or weight increases. The same type of data for donor BMI was reviewed. The proposed criteria were based on data that determined where 99% of transplant donors fall.

The Committee reviewed data to help identify organ specific exclusionary criteria such as bilirubin, liver biopsy with % micro vesicular fat, SGOT/AST, and % glomerulosclerosis. Deceased Donor Registration data of actual transplant donors from 2008 were analyzed to guide the Committee in setting the thresholds for the criteria listed above.

To help guide the discussion of which organs would be initially deemed to meet the eligible data definition, the Committee reviewed data that analyzed the match run data for kidney, liver, heart, and lung to assess when transplanted organs are placed (offers, centers).

The goal was to define “exhausting the list.” Members considered the organ specific data regarding the number of offers made for an organ to be accepted. The Committee considered identifying thresholds for the number of centers contacted or the number of patients offered an organ that might replace “exhausting the list.” While these data generated much discussion, it was decided that there were so many local and regional differences in the number of transplant programs and the size of the respective waiting lists that there was no one threshold that would be appropriate for all areas.

Expected Impact on Living Donors or Living Donation:

Not applicable.
Expected Impact on Specific Patient Populations:

There is no known direct impact on transplant candidates or recipients. Accurate data collection could result in identifying potential donors that were not previously identified. This would result in an increase in the number of organs for transplant, and together with process improvement would result in better quality of organs for transplant.

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

The proposed changes meet the HHS Program Goals to Promote the Efficient Management of the OPTN. Increasing the accuracy of data reporting is a process and system improvement that supports critical network functions of data collection.

Plan for Evaluating the Proposal:

I & E data will be analyzed periodically by the OPO Committee and staff to determine if there is more consistency in data reporting.

The OPO Committee will review the I & E data every six months following implementation of the policy changes.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The Board will consider this proposal at its June 2013 Board meeting. If approved, the proposed policy changes would be effective on September 1, 2013. Members involved in data reporting should review the policy changes and make any modifications to their own protocols or policies that relate to I & E data reporting. Any individual responsible for I & E death data reporting should attend one of the education sessions that will be offered by UNOS.

This proposal will require programming in UNetSM. There will be a minor change in UNetSM to the Online Help Documentation; however, no changes will be required to any of the data fields.

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<th>Communication Activities</th>
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<tr>
<td><strong>Type of Communication</strong></td>
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<td>Standard policy notice</td>
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<td>Article in UNOS Update</td>
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Compliance Monitoring:

UNOS Department of Evaluation and Quality (DEQ) staff will review death referral information reported to the OPTN during OPO onsite reviews. DEQ staff will verify that OPOs are using the definitions in policy to report death referral information to the OPTN.

Policy or Bylaw Proposal:

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

The Modifications to Appendix D, Section D.9 and Appendix K, Section 1 appear below with new language underlined and deleted language marked with strikethroughs.

7.0 DATA SUBMISSION REQUIREMENTS

7.1 REPORTING DEFINITIONS

7.1.1 – 7.1.5 [No Changes]

7.1.6 Imminent Neurological Death. The OPO must maintain documentation used to exclude any patient from the imminent neurological death data definition. Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral, a death of a patient:

- who meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law; and
- who has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no spontaneous breathing and has an absence of at least two additional brain stem reflexes, is considered an imminent neurological death.
Brain Stem Reflexes:
- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurologic death.

7.1.7 Although it is recognized that Eligible Death Definition. The OPO must maintain documentation used to exclude any patient from the eligible data definition. This definition does not include all potential donors. For reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years of age or younger who ultimately is legally declared brain dead according to hospital policy, independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits the following with all of the following characteristics:
- 75 years old or younger;
- Is legally declared dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law;
- Body weight 5 kg or greater;
- Body mass index (BMI) of 50 kg/m^2 or less;
- Has at least one kidney, liver, heart, or lung that is deemed to meet the eligible data definition as defined below:
  - The kidney would be initially deemed to meet the eligible data definition unless the donor has any of the following:
    - > 70 years of age
    - Age > 50-years with history of Type 1 diabetes for >20 years
    - Polycystic kidney disease
    - Terminal serum creatinine greater than 4.0 mg/dl
    - Glomerulosclerosis ≥ 30% by kidney biopsy
    - Chronic renal failure
    - No urine output ≥ 24 hours
  - The liver would be initially deemed to meet the eligible data definition unless the donor has any of the following:
    - Cirrhosis
    - Direct bilirubin/total bilirubin ≥ 15mg/dl over 24 hours with no trauma or transfusion
    - Portal hypertension
    - Macrostatosis ≥ 60% or bridging fibrosis ≥ stage III
    - Fulminant hepatic failure
    - Terminal AST or ALT > 3000 U/L
  - The heart would be initially deemed to meet the eligible data definition unless the donor has any of the following:
• > 60 years of age
• ≥ 45 years of age with a history of ≥10 years of HTN or ≥10 years of type 1 diabetes
• History of coronary artery bypass graft (CABG)
• History of coronary stent/intervention
• Current or past medical history of myocardial infarction (MI)
• Severe vessel diagnosis as supported by cardiac catheterization (e.g., >50% occlusion or 2+ vessel disease)
• Acute myocarditis and/or endocarditis
• Heart failure due to cardiomyopathy
• Internal defibrillator or pacemaker
• History of coronary artery bypass graft (CABG)
• History of coronary stent/intervention
• Current or past medical history of myocardial infarction (MI)
• Severe vessel diagnosis as supported by cardiac catheterization (e.g., >50% occlusion or 2+ vessel disease)
• Acute myocarditis and/or endocarditis
• Heart failure due to cardiomyopathy
• Internal defibrillator or pacemaker
• Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
• Serial echo results showing severe global hypokinesis
• Myxoma
• Congenital defects (whether surgically corrected or not)
  • The lung would be initially deemed to meet the eligible data definition unless the donor has any of the following:
    • > 65 years of age
    • Diagnosed COPD (e.g., emphysema)
    • Terminal PaO₂/FiO₂ <250 mmHg
    • Asthma (with daily prescription)
    • Asthma is the cause of death
    • Pulmonary fibrosis
    • Previous lobectomy
    • Multiple blebs documented on computed axial tomography (CAT) Scan
    • Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
    • Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an Eligible Death unless the donor meets any of the following criteria:
• The donor has no organs deemed to meet the eligible death data definition (as defined above), or;
• the donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplantation, or;
• if the donor exhibits any of the following:
  • Active infections (with a specific diagnosis) [Exclusions to the Definition of Eligible]
    • Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis, See "sepsis" below under "General"
    • Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including HTLV IV, Viral Encephalitis or Meningitis, Active Disseminated Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile Virus infection, SARS
- Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccioidioides, Active candidemia or invasive yeast infection
- Parasites: Active infection with Trypanosoma cruzi (Chagas’), Leishmania, Strongyloides, or Malaria (Plasmodium sp.)
- Prion: Creutzfeldt-Jacob Disease
- General [Exclusions to the Definition of Eligible]: Aplastic Anemia, Agranulocytosis
- Extreme Immaturity (<500 grams or gestational age of <32 weeks)
- Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
- Previous malignant neoplasms with current evident metastatic disease
- A history of melanoma
- Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma
- Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation
- Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis
- No discernable cause of death