

At-a-Glance

- **Proposal to Establish Kidney Paired Donation (KPD) Policy**
- **Affected/Proposed Policy and Bylaw:** Policy 13 (Kidney Paired Donation); OPTN Bylaws, Appendix E.5.F Kidney Paired Donation
- **Kidney Transplantation Committee**

This proposal converts the existing OPTN Kidney Paired Donation (KPD) Pilot Program rules, housed in the OPTN KPD Pilot Program Operational Guidelines, into OPTN policy. The full range of adverse actions will be available to the MPSC for violations of KPD policy, up to and including designation of member not in good standing. The policy also includes additional elements of potential donor informed consent that are specific to KPD and requirements for how the OPTN Contractor will conduct matching in the OPTN KPD Program. The proposed changes would consolidate all rules for the OPTN KPD Program into a single location and allow the MPSC to follow its standard processes for potential violations of KPD policy.

- **Affected Groups**
 - Lab Directors/Supervisors
 - Transplant Administrators
 - Transplant Physicians/Surgeons
 - PR/Public Education Staff
 - Transplant Program Directors
 - Transplant Social Workers
 - Kidney Candidates
 - Living Donors
- **Number of Potential Candidates Affected**

This proposal will impact approximately 200 candidates currently in the OPTN KPD Pilot Program as well as any candidates who may join the OPTN KPD Program in the future.
- **Compliance with OPTN Strategic Goals and Final Rule**

Overall, the OPTN KPD Program will increase the number of transplants. This proposal addresses the goals of promoting living donor safety and promoting transplant patient safety by addressing informed consent and blood type verification requirements.
- **Specific Requests for Comment**
 - Is it clear what the policy requirements are for Transplant Hospitals? Is it clear how the OPTN Contractor will audit these requirements?
 - Is the process for matching participants in the OPTN KPD Program transparent?
 - Are the informed consent elements that are specific to KPD appropriate and complete?

Proposal to Establish Kidney Paired Donation (KPD) Policy

Affected/Proposed Policy or Bylaw: Policy 13 (Kidney Paired Donation); OPTN Bylaws, Appendix E.5.F Kidney Paired Donation

Kidney Transplantation Committee

Summary and Goals of the Proposal:

This proposal converts the existing OPTN Kidney Paired Donation (KPD) Pilot Program rules, housed in the OPTN KPD Pilot Program Operational Guidelines, into OPTN policy. The full range of adverse actions will be available to the MPSC for violations of KPD policy, up to and including member not in good standing. The policy also includes additional elements of potential donor informed consent that are specific to KPD and requirements for how the OPTN Contractor will conduct matching in the OPTN KPD Program. The proposed changes would consolidate all rules for the OPTN KPD Program into a single location and allow the MPSC to follow its standard processes for potential violations of KPD policy.

Background and Significance of the Proposal:

Background on the KPD Pilot Program

The OPTN began looking into a national kidney paired donation system in 2004, and the Kidney Transplantation Committee developed a proposal for a national kidney paired donation program. At the time, there was some ambiguity as to whether kidney paired donation constituted “valuable consideration” under the National Organ Transplant Act (NOTA). Therefore, the OPTN could not approve or implement a national kidney paired donation system. As a result, the KPD proposal was sent out for public comment in 2004 and 2006, but it was not sent to the OPTN/UNOS Board of Directors for consideration at that time. It was not until Congress clarified NOTA in 2007 to explicitly state that KPD did not constitute valuable consideration that the OPTN could move forward. In March 2008, the OPTN/UNOS Kidney Transplantation Committee voted to forward the original KPD proposal to the Board of Directors with minimal changes. In June 2008, the Board of Directors approved a proposal for a national KPD Pilot Program¹. In November 2010, the Board of Directors approved the inclusion of non-directed donors and donor chains in the OPTN KPD Pilot Program.

The Kidney Transplantation Committee decided to begin with a pilot program so the OPTN could gain experience in kidney paired donation. The pilot program structure gave the Kidney Transplantation Committee and the OPTN Contractor the necessary flexibility to correct inefficiencies in the system, test new priorities, and clarify program requirements. The pilot program is governed by a set of rules called Operational Guidelines. The end of the pilot is when the Operational Guidelines are converted into policy. The OPTN Contractor has operated the OPTN KPD Pilot Program since October 2010.

Participating transplant hospitals signed a contract stating that they agreed to abide by the Operational Guidelines. If the Membership and Professional Standards Committee (MPSC) found a Transplant Hospital to be in material non-compliance with the Operational Guidelines, it could remove that Transplant Hospital from the OPTN KPD Pilot Program. There were no other actions available to the

¹ To view the briefing paper for the KPD Pilot Program as approved by the OPTN/UNOS Board of Directors in June 2008, please go to http://optn.transplant.hrsa.gov/SharedContentDocuments/KPD_Briefing_Paper_508V.pdf

MPSC. Once there is KPD policy, the review of compliance with KPD policy will take place using the same processes as for all other OPTN policy. With KPD policy, the full range of adverse actions will be available to the MPSC for violations of KPD policy, up to and including member not in good standing.

In December 2009, the Health Resources and Services Administration (HRSA) directed the OPTN to establish interim policies to govern kidney paired donation and to replace the Operational Guidelines. At the same time, HRSA also advised the OPTN to form a working group with OPTN Living Donor Committee Members and representatives from the American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), and the North American Transplant Coordinators Organization (NATCO) to develop draft elements to be included in OPTN living donor protocols. Because KPD also relies on the living donor informed consent and medical evaluation protocols, the development of KPD policy waited until the working group could make recommendations on overall living donor protocols. The working group released its recommendations in June 2011, and the Living Donor Committee released proposals to create policy for minimum requirements for living kidney donor medical evaluation and informed consent in September 2011. In anticipation of these proposals becoming policy, the KPD Work Group of the Kidney Transplantation Committee began drafting KPD policy.

The KPD Work Group of the Kidney Transplantation Committee has met twice a month beginning in July 2011 to develop KPD policy and to monitor OPTN KPD Pilot Program operations. The KPD Work Group includes Kidney Transplantation Committee representatives, Living Donor Committee representatives including a living donor, a Histocompatibility Committee representative, representatives from Members participating in the OPTN KPD Pilot Program, an OPO representative, and technical advisors who wrote the optimization algorithms used in the OPTN KPD Pilot Program. When drafting KPD policy, the KPD Work Group converted the Operational Guidelines into a policy format. The KPD Work Group also reviewed the Living Donor Committee's proposals on minimum requirements for the medical evaluation and informed consent of living kidney donors to determine if any additional elements relating specifically to KPD should be included in KPD policy.

In January and February 2012, the Kidney Transplantation, Living Donor, and Policy Oversight Committees reviewed the draft KPD policy. These Committees did not have any suggestions for additional requirements to include in KPD policy. On February 6, 2012, the Kidney Transplantation Committee voted to send the KPD policy language out for public comment. (18-Support, 0-Oppose, 0-Abstain)

Details of the Proposal

The KPD Operational Guidelines focused on what participating hospitals were required to do. KPD policy includes this same information but also delineates how the OPTN Contractor will operate the OPTN KPD Program.

All OPTN policies and bylaws, including living donation policies, apply to KPD exchanges, even those KPD exchanges not part of the OPTN KPD Program. Most of the proposed KPD policy applies only to the OPTN KPD Program. However, some elements of the donor informed consent apply to all KPD exchanges.

Table 1 shows the components of KPD policy and bylaws, the source of the requirements, the requirements included in each section, and any changes between the source and the KPD policy. The sections that apply to all KPD exchanges are noted in Table 1.

Table 1: Requirements in KPD Policy

Section	Source	Requirements	Revisions
OPTN Bylaws, Appendix E.5.F Kidney Paired Donation	OPTN Bylaws	Program must be approved to perform living donor kidney recoveries; Program must notify the OPTN Contractor in writing if it wishes to participate or cease participation in the OPTN KPD Program; Program must provide a primary and alternate KPD Contact to the OPTN Contractor	Individual contracts to participate no longer required; Notifications regarding participation must be in writing
Policy 13.2: Requirements for participation	KPD Operational Guidelines	Candidates must be on the kidney waiting list; Potential donors must be 18 or older; Potential donors must only be listed once in the OPTN KPD Program	No substantive changes
Policy 13.3: Candidate Informed Consent	KPD Operational Guidelines	Candidates must consent to: <ul style="list-style-type: none"> • Release of PHI • Participate in the OPTN KPD Program • Accepting a shipped kidney (if applicable) 	The release of PHI explicitly requires that the candidate consent for the OPTN contractor to share his PHI with the matched donor's hospital.
Policy 13.4: Donor Informed Consent	Newly developed and KPD Operational Guidelines	Transplants Hospitals must inform potential donors of: <ul style="list-style-type: none"> • Risks and benefits of KPD • Options for non-directed donors • OPTN KPD Program process Donors must consent to: <ul style="list-style-type: none"> • Release of PHI • Participate in the OPTN KPD Program • Shipping a kidney (if applicable) 	Risks and benefits of KPD (applies to all KPD exchanges); Options for non-directed donors (applies to all KPD exchanges); OPTN KPD Program process (applies to OPTN KPD Program only) The release of PHI explicitly requires that the potential donor consent for the OPTN contractor to share his PHI with the matched candidate's hospital.
Policy 13.5: Histocompatibility Requirements	KPD Operational Guidelines	Defines tissue typing requirements for candidates and donors; Typing must be at the level of split resolution and must be molecular	Requirements have been streamlined to include only requirements that are specific to the OPTN KPD Program

Policy 13.6.1: Requirements for Match Run Eligibility for Candidates	2008 KPD Pilot Program Proposal & KPD Manual Solution Operations (not previously specified in the Operational Guidelines)	Double ABO verification; Submitting required data; Status in OPTN KPD Program; Response to previous OPTN KPD offers	Double ABO verification is now required; Candidates no longer are limited to two active paired donors; Other elements are part of the KPD Manual Solution operations but are not included in the Operational Guidelines.
Policy 13.6.2: Requirements for Match Run Eligibility for Potential Donors	2008 KPD Pilot Program Proposal & KPD Manual Solution Operations (not previously specified in the Operational Guidelines)	Double ABO verification; Potential donor must complete evaluation and consent process; Submitting required data; Status in OPTN KPD Program; Response to previous OPTN KPD offers	Double ABO verification is now required; Other elements are part of the KPD Manual Solution operations but are not included in the Operational Guidelines.
Policy 13.6.3.1: Screening Criteria: Blood Type	KPD Manual Solution Operations (not previously specified in the Operational Guidelines)	Specifies which candidate and donor blood types will be matched in the OPTN KPD Program	Elements are part of KPD Manual Solution operations but are not included in the Operational Guidelines.
Policy 13.6.3.2: Screening Criteria: A ₂ and A ₂ B Matching	KPD Operational Guidelines	In order for a B or O candidate to be eligible to receive an A ₂ or A ₂ B donor kidney, the candidate must have a titer value of less than 1:8.	No substantive changes
Policy 13.6.3.3: Screening Criteria: Unacceptable Antigens	KPD Operational Guidelines	A candidate will not be matched with a potential donor who has one of the candidate's unacceptable antigens	No substantive changes
Policy 13.6.3.4: Candidate and Potential Donor Choices	2008 KPD Pilot Program Proposal & KPD Manual Solution Operations (not previously specified in the Operational Guidelines)	A candidate will not be matched with a donor who is outside the parameters specified in the candidate choices and vice versa	Elements are part of the KPD Manual Solution operations but are not included in the Operational Guidelines.

Policy 13.6.4: Prioritization Points	KPD Operational Guidelines and newly developed language for waiting time reinstatement	Specifies the characteristics of matches that receive points	<p>The waiting time points have changed from 2 points per match run to 0.07 points per day in order to keep the relative value of points the same if the match is run more often than once a month.</p> <p>KPD waiting time begins when a candidate is added to the KPD system and accrues when a candidate is active or inactive.</p> <p>The OPTN Contractor will reinstate KPD waiting if the candidate's graft fails within 90 days of transplant if appropriate documentation of graft failure is submitted.</p>
Policy 13.6.5.1: Two and Three Way Matches: Match Size	2008 KPD Pilot Program Proposal & KPD Manual Solution Operations (not previously specified in the Operational Guidelines	The OPTN Contractor will only match pairs in two-way exchanges, three-way exchanges, or donor chains.	Elements are part of the KPD Manual Solution operations but are not included in the Operational Guidelines.
Policy 13.6.5.2: Two and Three Way Matches: Logistical Requirements	2008 KPD Pilot Program Proposal & KPD Manual Solution Operations (not previously specified in the Operational Guidelines)	Donor surgeries must begin on the same day and only after all surgeons involved in the exchange agree to proceed.	Rather than beginning simultaneously, donor surgeries must begin on the same day and only when all surgeons involved in the exchange agree to proceed to accommodate exchanges taking place on opposite coasts and the shipping of kidneys.
Policy 13.6.6.1: Donor Chains: Chain Size	KPD Operational Guidelines	Chain cap is unlimited (pending programming). Until implementation, the chain cap is 20.	No substantive changes

Policy 13.6.6.2: Donor Chains: Logistical Requirements	KPD Operational Guidelines	A candidate must receive a kidney before his donor donates; A donor's surgery must be scheduled to occur within 3 weeks of the donor's paired recipient receiving a transplant; A chain ends with a donation to a candidate on the waiting list at the Transplant Hospital that entered the non-directed donor	No substantive changes
Policy 13.6.6.3: Donor Chains: What to Do When a Chain Breaks	KPD Operational Guidelines	Chains proceed up to the point where a candidate or donor refuses a match; Specifies circumstances when the final donor in a chain can be entered in a later match run	There are no longer requirements for what to do when a chain breaks based on the non-directed donor's blood type. See supporting evidence section.
Policy 13.7: Crossmatching Protocol	KPD Operational Guidelines	The candidate's Transplant Hospital must perform a preliminary crossmatch and report the results. The donor's Transplant Hospital is responsible for shipping the donor's blood to the location specified by the candidate's Transplant Hospital.	KPD Policy only requires a preliminary crossmatch before the donor recovery. The need for a final crossmatch is left up to the candidate's Transplant Hospital based on its crossmatching standards.
Policy 13.8: Transportation of Kidneys	Newly developed	In the OPTN KPD Program, the recovery Transplant Hospital must specify anybody who will be packaging, labeling, or transporting the kidney.	All elements are newly developed based on recommendations from the Living Donor Committee.
Policy 13.9: Rules for When Participants Can Meet	KPD Operational Guidelines	Members can only facilitate meetings after transplants have occurred and if both the candidate and the donor agree to meet. A Transplant Hospital must have a protocol and follow that protocol for when participants can meet.	No substantive changes

Policy 12.2: Informed Consent	Newly developed	The potential donor's Transplant Hospital must provide required information about the potential donor's paired candidate. The potential donor may request the same information about the matched candidate.	Clarification to Policy 12.2 for KPD situations
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In the current version of the KPD Operational Guidelines, the chain cap has been changed to be unlimited rather than 20 pairs, but the change is pending programming. The KPD policy also will have a chain cap of 20 pending implementation of the removal of the chain cap. Similarly, revisions to the number of active donors a candidate may have will also be pending programming.

When KPD waiting time goes from being based on the match run to being based on the add date, all candidates will have waiting time beginning on the add date to the OPTN KPD Program. Currently if candidates are ineligible for a match run because they are in a pending exchange, they would not accrue waiting time points simply because they were involved in a pending match, even if that match falls through. This new method allows candidates who have been in a pending match status to receive waiting time points so that candidates are not penalized for being part of a match that does not proceed to transplant. The change in KPD waiting time points and accrual will be effective pending programming.

The changes to Policy 12.2 are based on the proposal for the informed consent of living kidney donors sent out for public comment by the Living Donor Committee in Fall 2011. The Board of Directors will consider this proposal for the informed consent of living kidney donors in June 2012. If the Board does not approve the informed consent proposal, the KPD Work Group and the Kidney Transplantation Committee will remove the changes to Policy 12.2 from this KPD policy proposal before Board consideration.

Supporting Evidence and Modeling:

The majority of this proposal simply translates the requirements from one format to another. Therefore, the supporting evidence from the 2008 KPD policy proposal² still applies.

One substantive change is to eliminate requirements for what to do when a chain breaks based on blood type. When donor chains are identified, these chains often do not reach their full potential. A match would be refused at some point (also called a "chain break"), and the chain would end at that point in the chain. In the KPD Operational Guidelines, if a chain started by a blood type O donor breaks, the donor may be asked if he would like to wait until the next match run in order to identify a longer chain or to donate to a viable portion of the chain that had broken. Dickerson, Procaccia, and Sandholm simulated the impact of these requirements (under the currently best available estimates of realistic simulation parameters) and showed that allowing only longer chains to execute did not result in more transplants, likely due to the propensity of the non-directed donor to leave the pool after a certain

² To view the briefing paper for the KPD Pilot Program as approved by the OPTN/UNOS Board of Directors in June 2008, please go to http://optn.transplant.hrsa.gov/SharedContentDocuments/KPD_Briefing_Paper_508V.pdf

amount of time waiting.³ Two chains started by a blood type O non-directed donor have broken in the OPTN KPD Pilot Program. In both cases, the donor chose to donate to the shorter chain rather than to be entered in a later match run. As a result, the KPD Work Group recommended allowing chains to go forward up to the point where it breaks regardless of blood type.

Expected Impact on Living Donors or Living Donation:

This proposal requires KPD-specific informed consent for living donors participating in KPD. It also more clearly outlines the matching protocol for the OPTN KPD Program. As a result, living donors will have access to more information about the OPTN KPD Program. Additionally, this proposal could increase participation in KPD. Some Transplant Hospitals had difficulty in receiving approval to sign a contract to participate in the OPTN KPD Pilot Program and chose not to participate until policies were in place that would allow any member to participate without signing a separate contract. This proposal removes the barrier of Transplant Hospitals having to sign a separate contract.

Expected Impact on Specific Patient Populations:

This proposal has no known impact to specific patient populations. The overall OPTN KPD Program does increase access for highly sensitized candidates to receive a transplant by providing a larger pool of potential donors with whom they may match.

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

This proposal addresses the goals of promoting living donor safety and promoting transplant patient safety. For both living donors and candidates, this proposal requires double entry and verification of blood type before a potential donor or candidate can be included in a match run. By verifying blood type at an earlier point than is required elsewhere in policy, these policies reduce the likelihood of a laboratory or administrative error, which in turn reduces the likelihood that a candidate and potential donor with unsuitable blood types will match.

Additionally, the OPTN KPD Program will increase the number of transplants by allowing transplants to occur when the transplant opportunity would otherwise be lost. Please see the 2008 KPD Pilot Program proposal for more information.⁴

Plan for Evaluating the Proposal:

The KPD Work Group and Kidney Transplantation Committee will continue to use the following questions and metrics to evaluate the OPTN KPD Program:

- ***What questions or hypotheses are guiding the evaluation of the proposal?***
 - How many centers are participating in the system?

³ John P. Dickerson, Ariel D. Procaccia, and Tuomas Sandholm, "Optimizing Kidney Exchange with Transplant Chains: Theory and reality" (Accepted for publication at the Eleventh International Conference on Autonomous Agents and Multiagent Systems (AAMAS), Valencia, Spain, June 4-8, 2012).

⁴ To view the briefing paper for the KPD Pilot Program as approved by the OPTN/UNOS Board of Directors in June 2008, please go to http://optn.transplant.hrsa.gov/SharedContentDocuments/KPD_Briefing_Paper_508V.pdf

- How many pairs are registered in the system?
- How many matches are made through the system?
- How many matches made through the system proceed to transplant?
- What are the characteristics of candidates and potential donors?
- What are the characteristics of recipients and actual donors?
- What are the characteristics of matched pairs that do not proceed to transplant?
- What are the patient and graft survival outcomes for the transplants facilitated through the system?
- How many NDDs are registered in the program?
- How many matches include NDDs?
- How many NDDs have donated their kidneys through the KPD Program?
- How many transplants occurred as part of a chain started by a NDD?
- How many more transplants occurred because of the inclusion of NDDs and donor chains?
- ***Policy Performance Measures:***
 - Number of living donors and candidates registered in the KPD Program
 - Number of centers participating in the KPD Program
 - Number of matches run
 - Number of transplants facilitated by the KPD Program overall
 - Number of transplants, by candidate ABO, candidate calculated panel reactive antibody (CPRA) level, by candidate age, and by candidate diagnosis
 - Percent of matched pairs that proceed to transplant
 - Number of matched pairs that refuse the match before a crossmatch is run and associated refusal reasons
 - Patient and graft survival rates, rates of delayed graft function (not as a primary end point, but to evaluate impacts from the system overall)
 - Living donor outcomes
 - Number of NDDs registered in the program
 - Number of matches including NDDs
 - Number of NDDs who have donated their kidneys through the KPD Program
 - Number of chains found in the KPD Program
 - Number of chains that resulted in transplants
 - Median waiting time for pairs to find a match
 - Median time between segments in a chain
- ***Time Line for Evaluation:***

The KPD Work Group and Kidney Transplantation Committee will continue to review this information every six months.

Additional Data Collection:

There is no additional data collection resulting from converting the KPD Pilot Program Operational Guidelines into policy. All additional data collection relating to KPD was included in the 2008 KPD policy proposal and the 2010 donor chains proposal.

Expected Implementation Plan:

The Board will consider this proposal in November 2012. If approved by the Board, the majority of the policy language will be effective on February 1, 2013. The sections of policy that will be effective pending implementation are outlined below. The policy language that will be effective February 1, 2013 is presented separately from the policy language that is effective pending implementation in the Policy and Bylaw Proposal section of this document.

This proposal will require programming in the KPDSM application. Some of the KPD bylaws and policy may be in effect before all field labels are updated because it will not hinder Transplant Hospitals’ ability to comply with the policy. The elimination of the limit on the number of donors a potential candidate can have and the change to the waiting time points will require programming in the KPDSM application, and the related policy language will be effective once programming is complete. Finally, the revision to the chain cap will require a change to the optimization algorithm. That requirement in KPD policy will be effective pending programming as well.

If approved, Transplant Hospitals will need:

- To notify the OPTN Contractor in writing if it wishes to participate or to cease participating in the OPTN KPD Program;
- To update relevant informed consent processes; and
- To create a plan for transporting each kidney that is part of an OPTN KPD exchange prior to the kidney recovery surgery.

Existing informed consent templates will be updated to meet the new policy requirements.

Upon implementation, the Membership and Professional Standards Committee (MPSC) will use its standard processes, contained in the OPTN Bylaws, for monitoring member compliance. Violations of KPD policy can result in the full range of adverse actions, up to and including member not in good standing.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	Members	E-newsletter	30 days after passed by Board
Website Enhancement	General public, members	Web-posting	After implementation date

Education/Training Activities			
Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
Informed Consent Templates	Transplant surgeons, transplant coordinators	Posted in KPD SM application, member newsletter, and OPTN website	TBD

Compliance Monitoring:

During on-site reviews, the UNOS Department of Evaluation and Quality (DEQ) staff reviews and verifies donor recovery transplant centers’ policies and procedures, and verifies the presence and accuracy of the documentation for a sample of records during site surveys.

Policy 13.2

DEQ staff will verify the following:

- Donors are at least 18 years old

Policy 13.3

During on-site reviews of candidates’ transplant centers, DEQ staff will verify the following documentation in the candidate records:

- Signed protected health information release from each candidate
- Signed consent from each candidate to participate in the Kidney Paired Donation (KPD) Program
- Signed consent to accept a shipped kidney from each candidate who receives a shipped kidney

Policy 13.4

During on-site reviews of donors’ transplant centers, DEQ staff will verify that the donor provided informed consent required by Policy 12.2 and the donor records contain all of the following

- Documentation that the Transplant Hospital reviewed the potential risks and benefits of participation listed in Policy 13.4.2 with the potential donor
- Documentation that the Transplant Hospital disclosed the donation options listed in Policy 13.4.3 with any non-directed donors in KPD exchanges
- Documentation that the Transplant Hospital informed any potential KPD donors of the KPD program elements listed in Policy 13.4.4
- Signed consent to ship the kidney from each living donor whose kidney was shipped
- Signed protected health information release from each potential living donor
- Signed consent from each potential living donor to participate in the KPD Program

Policy 13.8

During on-site reviews of recovery Transplant Hospitals, DEQ staff will verify the following documentation in the KPD donor records:

- Name of person(s) who packaged the kidney
- Name of person(s) who labeled the kidney
- Name of person(s) who transported the kidney
- Time and date that the names were recorded

DEQ staff will verify that the recording time was before the donor entered the operating room for the kidney recovery surgery.

Policy 13.9

During on-site reviews of transplant centers, DEQ staff will review the transplant center's protocol for when KPD participants can meet, and will verify that the protocol was followed.

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if the center does not comply with the requirements of Policy 13.0 and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy and Bylaw Proposal:

The proposed policy language is organized into three sections: policy additions that will not require programming; changes to pending policy proposals; and policy changes that will require programming. For the convenience of the reader, the proposed policy language for Policy 13 (Kidney Paired Donation) appears below without underlines as the entire section is new.

13 KIDNEY PAIRED DONATION

13.1 Scope of Policy

Unless otherwise stated, references to potential donors and donors within this policy are specific to KPD potential donors and donors and references to candidates and recipients are specific to KPD candidates and recipients.

13.2 Requirements for Participation in the OPTN KPD Program

13.2.1 Candidates

In order to participate in the OPTN KPD program, candidates must be registered on the deceased donor kidney waiting list at the Transplant Hospital that wishes to enroll the candidate in the OPTN KPD Program.

13.2.2 Potential Donors

In order to participate in OPTN KPD Program, potential donors must comply with *all* of the following requirements:

1. Be aged at least 18 years old
2. Not be currently listed as a potential donor for any other candidate registered in the OPTN KPD Program

13.3 Informed Consent for Candidates

13.3.1 Release of Protected Health Information

The candidate's Transplant Hospital must receive written consent from the candidate entered in the OPTN KPD Program to allow hospitals to share protected health information (PHI) with other Members participating in the OPTN KPD program. The release must allow the OPTN Contractor to share the candidate's PHI with the Transplant Hospital of the candidate's matched potential donor. The candidate's Transplant Hospital must maintain this documentation in the candidate's chart.

13.3.2 Agreement to Participate

The candidate's Transplant Hospital must receive written consent from the candidate to participate in the OPTN KPD program. The candidate's Transplant Hospital must maintain documentation of the candidate's informed consent in the candidate's chart.

13.3.3 Agreement to Accept a Shipped Kidney

If a candidate entered in the OPTN KPD Program is willing to receive a shipped kidney, the candidate's Transplant Hospital must receive written consent from the candidate in order for the candidate to receive a shipped kidney. The candidate's Transplant Hospital must maintain this documentation in the candidate's chart.

13.4 Informed Consent for Potential Donors

13.4.1 General Potential Donor Informed Consent

For any KPD exchange, the potential donor's Transplant Hospital is responsible for receiving informed consent from potential donors as provided in Policy 12.2 with these modifications:

While the Recovery Hospital is responsible for informed consent in Policy 12.2, the potential donor's Transplant Hospital is responsible for informed consent in this policy, regardless of whether they perform the organ recovery. If a different Transplant Hospital performs the organ recovery, the Recovery Hospital must comply with Policy 12.2.

13.4.2 KPD-Specific Elements

For any KPD exchange, the potential donor's Transplant Hospital must inform the potential donor of the following risks and benefits of participation:

1. The possibility of helping more than one candidate receive a transplant
2. The possibility that the potential donor may have to wait to find a match
3. The possibility that the potential donor might have to wait longer to donate after a match has been identified because of logistical complexities

4. The possibility that the a candidate might not receive a transplant because of an unexpected issue with a potential donor's kidney found during or after surgery
5. The possibility that the potential donor's kidney might not be transplanted or the potential donor's intended candidate might not receive a transplant because of unexpected events
6. The possibility that the matched candidate's insurance might not cover all travel costs if the potential donor travels to the matched candidate's Transplant Hospital
7. The possibility that the donor's paired recipient and the donor's matched recipient might not have equal outcomes
8. The possibility of the donor's name appearing on the matched recipient's estimation of benefits.

For any KPD exchange, the potential donor's Transplant Hospital must inform the potential donor of the potential donor's right to withdraw their participation at any time.

The potential donor's Transplant Hospital must maintain this documentation in the potential donor's chart.

13.4.3 Additional Elements for Non-Directed Donors

For any KPD exchange, the potential donor's Transplant Hospital must inform non-directed donors (NDDs) that they have the following options:

- Participating in kidney paired donation
- Donating directly to the local deceased donor list
- Any other options available in the potential donor's area.

The potential donor's Transplant Hospital must maintain this documentation in the potential donor's chart.

13.4.4 OPTN KPD Program Process Consents

The potential donor's Transplant Hospital must inform potential donors entered in the OPTN KPD Program of the following elements of the OPTN KPD Program:

1. Potential donors do not choose with whom they match. A potential donor or a candidate may decline a match after it has been found.
2. Matching requirements in Policy 13.6.5 and Policy 13.6.6
3. Rules for when Members may facilitate meetings between donors and recipients in the OPTN KPD Program in Policy 13.9

The potential donor's Transplant Hospital must maintain documentation in the potential donor's chart that the potential donor has been informed of each element.

13.4.5 Consent to Ship a Kidney

For any KPD exchange, if the potential donor chooses to allow his kidney to be shipped, the potential donor's Transplant Hospital must receive written consent from the potential donor showing that the potential donor has been informed of the potential risks of shipping a kidney. The potential donor's Transplant Hospital must maintain this documentation in the potential donor's chart.

13.4.6 Release of Protected Health Information

The potential donor's Transplant Hospital must receive written consent from the potential donor entered in the OPTN KPD Program to allow the Transplant Hospital to share protected health information (PHI) with other Members participating in the OPTN KPD program. The release must allow the OPTN Contractor to share the potential donor's PHI with the Transplant Hospital of the potential donor's matched candidate. The potential donor's Transplant Hospital must maintain this documentation in the potential donor's chart.

13.4.7 Agreement to Participate

The potential donor's Transplant Hospital must receive written consent from the potential donor to participate in the OPTN KPD Program. The potential donor's Transplant Hospital must maintain documentation of the potential donor's informed consent in the potential donor's chart.

13.5 Histocompatibility Testing

In the OPTN KPD Program, the candidate's Transplant Hospital is responsible for performing HLA-A, -B, -Bw4, -Bw6, and, -DR antigen typing on the candidate. If the candidate has antibodies against HLA-DQA or -DPA or -DPB, the candidate's Transplant Hospital is responsible for performing HLA-DQA, -DPA, or -DPB antigen typing on the candidate.

In the OPTN KPD Program, the potential donor's Transplant Hospital is responsible for performing HLA-A, -B, -Bw4, -Bw6, -Cw, -DR, -DR51, -DR52, -DR53, and, -DQ antigen typing on the potential donor.

In the OPTN KPD Program, HLA typing must be performed at the level of split resolution. The primary HLA typing method must be molecular.

13.6 Matching Within the OPTN KPD Program

13.6.1 Requirements for Match Run Eligibility for Candidates

The OPTN KPD Program will only match candidates that comply with *all* of the following requirements:

1. The candidate's Transplant Hospital must comply with Policy 3.1.2
2. The candidate's Transplant Hospital must complete the informed consent process in Policy 13.2

3. The candidate's Transplant Hospital must submit the required fields below to the OPTN Contractor
 - a. Candidate Details
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Whether the candidate has signed an agreement to participate in the OPTN KPD Program
 - Whether the candidate has signed a release of protected health information
 - Whether the candidate is a prior living donor
 - KPD status
 - b. Candidate Choices
 - Whether the candidate would be willing to travel, and, if so, the Transplant Hospitals to which a candidate would be willing to travel
 - Whether the candidate is willing to accept a shipped kidney, and, if so, from which Transplant Hospitals the candidate would be willing to accept a shipped kidney
 - Minimum and maximum acceptable donor age
 - Minimum acceptable donor creatinine clearance
 - Maximum acceptable donor BMI
 - Maximum acceptable systolic and diastolic blood pressure
 - Whether the candidate is willing to accept a hepatitis B core antibody positive donor, a CMV positive donor, and an EBV positive donor
 - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
 - c. HLA
 - HLA-A antigen typing
 - HLA-B antigen typing
 - HLA-Bw4 antigen typing
 - HLA-Bw6 antigen typing
 - HLA-DR antigen typing
4. The candidate must be in an active status in the OPTN KPD Program
5. The candidate must have at least one and no more than two active and eligible potential donor registered in the OPTN KPD Program
6. The candidate's Transplant Hospital must submit a response for all previous match offers for the candidate in the OPTN KPD Program
7. The candidate must not be in a pending exchange in the OPTN KPD Program

13.6.2 Requirements for Match Run Eligibility for Potential Donors

The OPTN KPD Program will only match potential donors that comply with *all* of the following requirements:

1. The potential donor's Transplant Hospital must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications
 - a. The potential donor's Transplant Hospital must report the potential donor's actual blood type to the OPTN Contractor
 - b. Someone, other than the person who reported the potential donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential donor's actual blood type to the OPTN Contractor
 - c. The potential donor is not eligible for a KPD match run until the Transplant Hospital reports two identical blood types
2. The potential donor's Transplant Hospital must complete the informed consent process in Policy 13.3
3. The potential donor's Transplant Hospital must complete the medical evaluation process in Policy 12.3
4. The potential donor's Transplant Hospital must submit the required fields below to the OPTN Contractor
 - a. Donor Details
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Height and weight
 - Whether the potential donor is a non-directed donor;
 - If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate
 - Whether the potential donor has signed an agreement to participate in the OPTN KPD Program
 - Whether the potential donor has signed a release of protected health information
 - Whether the potential donor has signed an informed consent as required in policy
 - Whether the potential donor has undergone a medical evaluation as required in policy
 - Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society

- KPD status
- b. Clinical Information
 - The number of anti-hypertensive medications the donor is on
 - Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
 - Creatinine clearance, date, and method
 - Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
 - c. Donor Choices
 - Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel
 - Whether the potential donor is willing to ship a kidney
 - Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney
 - Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain
 - d. HLA
 - HLA-A antigen typing
 - HLA-B antigen typing
 - HLA-Bw4 and –Bw6 antigen typing
 - HLA-Cw antigen typing
 - HLA-DR antigen typing
 - HLA-DR51, -DR52, and –DR53 antigen typing
 - HLA-DQ antigen typing
5. The potential donor must be in an active status in the OPTN KPD Program
 6. The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program
 7. The potential donor’s Transplant Hospital must submit a response for all previous match offers for the potential donor in the OPTN KPD Program
 8. The potential donor must not be in a pending exchange in the OPTN KPD Program.

13.6.3 Screening Criteria

13.6.3.1 Blood Type

The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types as defined in Table 13-1. Fields with a “●” indicate identical blood type matches. Fields with a “○” indicate permissible blood type matches. Fields with a “○*” indicate permissible blood type matches providing the candidates meets the requirements in Policy 13.6.3.2. Fields with a “○” indicate impermissible blood type matches.

		Candidate's Blood Type			
		O	A or A1 or A2	B	AB or A1B or A2B
Donor's Blood Type	O	●	○	○	○
	A	○	●	○	○
	A1	○	●	○	○
	A2	○*	●	○*	○
	B	○	○	●	○
	AB	○	○	○	●
	A1B	○	○	○	●
	A2B	○	○	○*	●

Table 13-2: Blood Typing for KPD

13.6.3.2 A₂ and A₂B Matching

In order for a blood type B candidate to be eligible to be matched to a blood type A₂ or A₂B potential donor, or for a blood type O candidate to be eligible to match to a blood type A₂ potential donor in the OPTN KPD Program, *all* of the following conditions must be met:

1. The candidate must have a titer value less than 1:8
2. The candidate's Transplant Hospital must report to the OPTN Contractor the candidate's titer value and date of the test.

13.6.3.3 Unacceptable Antigens

A Transplant Hospital may specify any unacceptable antigens it will not accept for its candidates. The OPTN Contractor will not match the candidate with any potential who has one of the candidate's unacceptable antigens entered as an HLA value.

13.6.3.4 Candidate and Potential Donor Choices

A Transplant Hospital may specify criteria it will not accept for any of its candidates as outlined in Policy 13.6.1-3(b) or potential donors as outlined in Policy 13.6.2-6(c). The OPTN Contractor will not match the candidates with potential donors who fall outside the specified criteria or potential donors with candidates who fall outside the specified criteria.

13.6.4 Prioritization Points

The OPTN Contractor will identify all possible matches and exchanges from the list of potential donors and candidates, assign points to each match according to Table 13-2, and select the set of exchanges with the highest point values.

All OPTN KPD Program matches receive 100 base points. Matches will receive additional points as described in Table 13-2.

If the:	Then, the match will receive:
Candidate is a zero antigen mismatch with a potential donor	200 points
Candidate is highly sensitized	125 points
Candidate is a prior living organ donor	150 points
Candidate is aged less than 18 years	100 points
Candidate participated in a previous KPD match run	2 points per match run
Candidate and potential donor are in the same region	25 points
Candidate and potential donor are in the same local unit	50 points
Candidate and potential donor are registered at the same Transplant Hospital	75 points
Potential donor has at least one of the candidate's other antibody specificities	- 5 points

Table 13-2: KPD Points

The OPTN Contractor will reinstate KPD waiting time, without interruption, to KPD candidates when immediate and permanent non-function of the kidney occurs within 90 days of any kidney transplant, as evidenced by one of the following:

- The removal of the organ
- Dialysis treatment 90 days after transplant
- Creatinine clearance (CrCl) or calculated Glomerular filtration rate (GFR) less than or equal to 20 ml/min 90 days after transplant.

The OPTN Contractor will reinstate KPD waiting time after receiving a completed KPD waiting time reinstatement form and will notify the candidate's Transplant Hospital of the candidate's KPD waiting time reinstatement.

13.6.5 Two and Three Way Matches

13.6.5.1 Match Size

The OPTN Contractor will match donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor as outlined in Policy 13.6.6.

13.6.5.2 Logistical Requirements

In two-way or three-way exchanges in the OPTN KPD Program, all donor surgeries involved in the exchange must begin on the same day and only after all donor surgeons involved in the exchange agree to proceed.

13.6.6 Donor Chains

13.6.6.1 Chain Size

In the OPTN KPD Program, donor chains will be limited to 20 donor-candidate pairs.

13.6.6.2 Logistical Requirements

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. Donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain.

13.6.6.3 What to Do When a Chain Breaks

In the OPTN KPD Program, a donor chain will proceed until a candidate or potential donor refuses a match offer.

If a candidate or potential donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a candidate or potential donor refuses a match, may be entered in the next match run to repair the donor chain if *all* of the following conditions are met:

1. The operating room dates are not set for a chain at the time of the next match run
2. The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match
3. The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.

13.7 Crossmatching Protocol

The candidate's Transplant Hospital must perform a preliminary crossmatch for candidates in the OPTN KPD Program before the matched donor's recovery procedure.

The potential donor's Transplant Hospital is responsible for shipping the potential donor's blood sample to the matched candidate's Transplant Hospital or the laboratory specified by the matched candidate's Transplant Hospital.

The candidate's Transplant Hospital is responsible for running the crossmatch and reporting the results to the OPTN Contractor and the matched donor's Transplant Hospital.

13.8 Transportation of Kidneys

For any KPD exchange, the recovery Transplant Hospital is responsible for packaging, labeling, and transporting kidneys from donors as provided in Policy 12.7.

In the OPTN KPD Program, the recipient's Transplant Hospital must specify the location where the recovery Transplant Hospital must deliver the kidney. The recovery Transplant Hospital must then document the name and telephone number of every person or company who will package, label, or transport the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the recipient's Transplant Hospital along with the date and time that the name is documented. The recovery Transplant Hospital must complete this documentation before the potential donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's chart.

13.9 Rules for When Donors and Recipients Can Meet

The following rules apply to meetings facilitated by an OPTN Member between donors and matched recipients that participated in an OPTN KPD Program exchange. These rules do not apply to meetings between potential donors and paired candidates.

Members can facilitate a meeting between donors and recipients that participated in an OPTN KPD Program exchange only if *all* of the follow conditions are met:

1. All the donors and recipients participating in the meeting agree to meet
2. The meeting occurs after the transplant concludes
3. The Transplant Hospital establishes a written protocol for when donors and recipients can meet. This protocol must include, at a minimum, the timing of the meeting and what staff must attend the meeting.
4. Transplant Hospital complies with their written protocol for when donors and recipients can meet. The Transplant Hospital must maintain documentation of compliance in the donor's or recipient's chart.

13.10 Definitions

- *Chain* – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate's paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.
- *Exchange* – a set of matches that form a chain, a two-way exchange, or a three-way exchange.
- *Match* – a donor and his matched candidate
- *Match Run* – procedure used to generate a set of exchanges
- *Matched candidate* – the candidate that a KPD match run identifies as a potential recipient of a donor's kidney
- *Matched donor* – a donor identified by a KPD match run as a potential donor for a candidate

- *Matched recipient* – a matched candidate that has received a transplant
- *Non-Directed Donor (NDD)* - a donor that enters KPD without a paired candidate
- *Other antibody specificities*- antigens that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens.
- *Pair* – a donor and his paired candidate
- *Paired candidate* – the candidate to whom a donor intended to donate his organ before entering into KPD
- *Paired Donation of Human Kidneys (KPD)* – the donation and receipt of human kidneys under the following circumstances:
 - An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.
 - A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.
 - The first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.
 - If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.
 - All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.
 - Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.
- *Paired donor* – a donor who intended to donate his organ, before entering into KPD, to his paired candidate
- *Paired Recipient*- a paired candidate that has received a transplant
- *Potential donor's Transplant Hospital*- the Transplant Hospital that enters the potential donor in a KPD program
- *Three-way exchange*- a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.
- *Two-way exchange* – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.
- *Unacceptable antigens*- antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens.

For Policy 12.2 (Informed Consent of Living Kidney Donors) and OPTN Bylaws, Appendix E, proposed language is underlined (example) and deleted language is struck through (example). For Policy 12 (Living Donation), language that is proposed or deleted is in reference to the 2011 public comment proposal that has not yet been adopted by the OPTN Board of Directors.

12.2 Informed Consent of Living Kidney Donors

- f. ~~The stipulation that the recovery hospital must provide potential donors with both national and program specific transplant recipient outcomes from the most recent SRTR center specific reports. This information must include the hospital's 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all CMS outcome requirements not being met by the transplant hospital.~~

Disclosure of both national and program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific reports. This information must include the Recovery Hospital's 1-year recipient and graft survival information, national 1-year recipient and graft survival information, and notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not met by the Recovery Hospital.

In a kidney paired donation arrangement, the potential donor's Transplant Hospital must provide the information required in the above paragraph about the paired candidate's Transplant Hospital.

- h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.
- The donor must be made aware that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.
 - ~~Potential donors must be provided a realistic estimate of the likelihood of successful transplantation for the transplant candidate, given the specific set of risk factors that the transplant candidate may have for any increased morbidity or mortality. The donor must be informed if the transplant candidate has risk factors for increased morbidity or mortality that the transplant candidate does not wish disclosed.~~
 - Disclosure of a realistic estimate of the likelihood of successful transplantation for the potential recipient, given the specific set of risk factors that the potential recipient may have for any increased morbidity or mortality. The potential living donor must be informed if the potential recipient has risk factors for increased morbidity or mortality that the potential recipient does not wish disclosed.
 - In a kidney paired donation arrangement, the potential donor's Transplant Hospital must provide the information required in the above paragraph about the paired candidate.

- In a kidney paired donation arrangement, if the potential donor requests information on the matched candidate, the matched candidate's Transplant Hospital must provide the following information to the potential donor's Transplant Hospital to be shared with the potential donor:
 - The matched candidate's Transplant Hospital's 1-year patient and graft survival
 - Notification about all CMS outcome requirements not being met by the matched candidate's Transplant Hospital, and
 - A realistic estimate of the likelihood of successful transplantation for the potential donor's matched candidate, given the specific set of risk factors that the matched candidate may have for any increased morbidity or mortality.

OPTN Bylaws, Appendix E

E.5. Kidney Transplant Programs that Perform Living Donor Recovery

~~F. Kidney Paired Donation~~

~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

F. Kidney Paired Donation (KPD)

Members that choose to participate in any OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the Transplant Hospital decides to participate in an OPTN KPD program. A Transplant Hospital must notify the OPTN Contractor in writing if it decides to quit its participation in an OPTN KPD program.
3. Provide to the OPTN Contractor a primary and alternate kidney paired donation contact that is a member of the Hospital's staff.

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

For Policies 13.6.1, 13.6.4, and 13.6.6, proposed language is underlined (example) and deleted language is struck through (~~example~~). For these sections, language that is proposed or deleted is in reference to the above proposal but would require programming before implementation.

Pending implementation:

13.6.1 Requirements for Match Run Eligibility for Candidates

The OPTN KPD Program will only match candidates that comply with *all* of the following requirements:

1. The candidate's Transplant Hospital must comply with Policy 3.1.2
2. The candidate's Transplant Hospital must complete the informed consent process in Policy 13.2
3. The candidate's Transplant Hospital must submit the required fields below to the OPTN Contractor
 - a. Candidate Details
 - Last name
 - First name
 - SSN
 - Date of birth
 - Gender
 - Ethnicity/Race
 - ABO
 - Whether the candidate has signed an agreement to participate in the OPTN KPD Program
 - Whether the candidate has signed a release of protected health information
 - Whether the candidate is a prior living donor
 - KPD status
 - b. Candidate Choices
 - Whether the candidate would be willing to travel, and, if so, the Transplant Hospitals to which a candidate would be willing to travel
 - Whether the candidate is willing to accept a shipped kidney, and, if so, from which Transplant Hospitals the candidate would be willing to accept a shipped kidney
 - Minimum and maximum acceptable donor age
 - Minimum acceptable donor creatinine clearance
 - Maximum acceptable donor BMI
 - Maximum acceptable systolic and diastolic blood pressure
 - Whether the candidate is willing to accept a hepatitis B core antibody positive donor, a CMV positive donor, and an EBV positive donor
 - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney
 - c. HLA

- HLA-A antigen typing
 - HLA-B antigen typing
 - HLA-Bw4 antigen typing
 - HLA-Bw6 antigen typing
 - HLA-DR antigen typing
4. The candidate must be in an active status in the OPTN KPD Program
 5. The candidate must have at least one ~~and no more than two~~ active and eligible potential donor registered in the OPTN KPD Program
 6. The candidate’s Transplant Hospital must submit a response for all previous match offers for the candidate in the OPTN KPD Program
 7. The candidate must not be in a pending exchange in the OPTN KPD Program

13.6.4 Prioritization Points

The OPTN Contractor will identify all possible matches and exchanges from the list of potential donors and candidates, assign points to each match according to Table 13-2, and select the set of exchanges with the highest point values.

All OPTN KPD Program matches receive 100 base points. Matches will receive additional points as described in Table 13-2.

If the:	Then, the match will receive:
Candidate is a zero antigen mismatch with a potential donor	200 points
Candidate is highly sensitized	125 points
Candidate is a prior living organ donor	150 points
Candidate is aged less than 18 years	100 points
Candidate participated in a previous KPD match run Candidate is entered in the OPTN KPD Program at the time of the match run	2 points per match run <u>0.07 points per day in the OPTN KPD Program</u>
Candidate and potential donor are in the same region	25 points
Candidate and potential donor are in the same local unit	50 points
Candidate and potential donor are registered at the same Transplant Hospital	75 points
Potential donor has at least one of the candidate’s other antibody specificities	- 5 points

Table 13-2: KPD Points

KPD waiting time begins on the day the candidate’s Transplant Hospital enters the candidate in the OPTN KPD Program. A candidate will accrue KPD waiting at both an active and an inactive status in the OPTN KPD Program.

The OPTN Contractor will reinstate KPD waiting time, without interruption, to KPD candidates when immediate and permanent non-function of the kidney occurs within 90 days of any kidney transplant, as evidenced by one of the following:

- The removal of the organ

- Dialysis treatment 90 days after transplant
- Creatinine clearance (CrCl) or calculated Glomerular filtration rate (GFR) less than or equal to 20 ml/min 90 days after transplant.

The OPTN Contractor will reinstate KPD waiting time after receiving a completed KPD waiting time reinstatement form and will notify the candidate's Transplant Hospital of the candidate's KPD waiting time reinstatement.

13.6.6 Donor Chains

13.6.6.1 Chain Size

In the OPTN KPD Program, ~~donor chains will be limited to 20 donor candidate pairs.~~ there is no limit on the length of the donor chains.