

## *Briefing to the OPTN Board of Directors on* **Update Kidney Paired Donation Policy**

*OPTN Kidney Transplantation Committee*

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# Update Kidney Paired Donation Policy

<i>Affected Policies:</i>	<p>1.2: Definitions</p> <p>13.3: Informed Consent for KPD Candidates</p> <p>13.4: Informed Consent for KPD Donors</p> <p>13.4.D: Additional Requirements for Non-Directed Donors</p> <p>13.4.E: Additional Requirements for Bridge Donors</p> <p>13.7.G: OPTN KPD Waiting Time Reinstatement</p> <p>13.11: Receiving and Accepting KPD Match Offers</p> <p>13.11.A: Requesting a Deadline Extension for a KPD Exchange</p> <p>14.6.B: Placement of Non-Directed Living Donor Organs</p>
<i>Sponsoring Committee:</i>	Kidney Transplantation
<i>Public Comment Period:</i>	August 3, 2022-September 28, 2022
<i>Board of Directors Meeting:</i>	December 5, 2022

## Executive Summary

The OPTN's Kidney Paired Donation Pilot Program (KPDPP) has been operational since 2010 and is governed by *OPTN Policy 13: Kidney Paired Donation*. Kidney Paired Donation (KPD) is a process that matches one medically incompatible living donor-candidate pair with another, so the donor in each pair is medically compatible with the candidate in the other pair. By exchanging living donors, each candidate can receive a compatible transplant. These "exchanges" can consist of several candidate-donor pairs, creating KPD "chains."<sup>1</sup>

The OPTN Kidney Transplantation Committee (the Committee) proposes a series of minor modifications to OPTN KPD policy to provide clarity to and align policy language with, other OPTN policies and improve efficiency of the OPTN KPDPP program. The proposed modifications will:

- Shorten match offer and evaluation deadlines
- Establish scheduled recovery and transplant deadlines
- Adjust policy to prevent termination of exchanges due to administrative lapses
- Update informed consent policies to provide clarity, emphasize donor autonomy, and align requirements with those in OPTN Living Donor policy

In considering public comment feedback: the Committee proposes post-public comment changes:

- Updating the deadline from match offer to scheduled recovery and transplant, to promote increased donor autonomy
- Establish an additional deadline for programs in an exchange to agree upon a date and time for recovery surgery, to improve efficiency
- Update bridge donor informed consent, to further emphasize donor autonomy
- Additional informed consent and administrative policy language clarifications

This proposal is an initial step towards bringing KPD policy up to date and improving the efficiency of the OPTN KPDPP.

<sup>1</sup> Kidney Paired Donation, United Network for Organ Sharing. <https://unos.org/transplant/kidney-paired-donation/>

## Purpose

OPTN KPD Policy was last updated in 2015. Since that time, the practice of KPD has evolved, and changes are warranted to clarify and bring KPD Policy up to date. The purpose of this proposal is to align *OPTN Policy 13: Kidney Paired Donation* with other OPTN policies, clarify language and requirements, bring administrative OPTN KPD policies up to date with current practices, and to increase efficiency within the KPD match offer, exchange, and transplant processes. This proposal also includes updates to KPD informed consent requirements to improve clarity and emphasize donor autonomy. This proposal will also update administrative requirements for the OPTN KPDPP, to align with current practices and improve program efficiency.

## Background

The original OPTN KPD Workgroup (the Workgroup) formed in 2004, and developed a pilot national KPD program. This program, the OPTN KPDPP, became operational in 2010.<sup>2,3</sup> Over the last decade, the Workgroup has monitored the progress of the OPTN KPDPP, periodically updating policy as necessary to improve the success of the program.

The OPTN KPD Workgroup re-formed in 2021 with representation from the following OPTN Committees:

- Kidney Transplantation
- Living Donor
- Histocompatibility
- Minority Affairs
- Patient Affairs
- Transplant Coordinators
- Transplant Administrators

The Workgroup performed a holistic review of *OPTN Policy 13: Kidney Paired Donation*, identifying language in need of clarification and alignment with current practices and other relevant parts of OPTN policy. During this review, the Workgroup determined several small policy modifications were appropriate, to improve efficiency and clarity in KPD processes.

## Proposal for Board Consideration

The Committee proposes a series of small modifications to update, clarify, and align OPTN KPD policy. These modifications are expanded upon below, and include changes to OPTN KPDPP administrative policies, informed consent policies for both KPD donors and candidates, and other minor language updates.

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<sup>2</sup> As a pilot, the OPTN KPDPP was governed by the official Operational Guidelines developed by the KPD Workgroup. These Operational Guidelines were not subject to the public comment process, and so allowed the KPD Workgroup the flexibility to adjust the rules and processes of the pilot program as necessary. In 2012, the KPD Workgroup began the process of revising and moving the KPDPP Operational Guidelines to OPTN Policy, in an effort to transition the program out of its pilot stage. The Operational Guidelines were revised a total of 10 times before their ultimate removal in October 2021, at the October 8, 2021 meeting of the OPTN Kidney Transplantation Committee.

<sup>3</sup>OPTN Kidney Transplantation Committee Meeting Summary, October 8, 2021.

[https://optn.transplant.hrsa.gov/media/4hzlnxhy/20211008\\_kidney\\_meeting\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4hzlnxhy/20211008_kidney_meeting_summary.pdf)

## Administrative Updates

The Committee proposes modifications to OPTN administrative policies for the OPTN KPDPP, including updates to match offer review deadlines and the deadline extension request process. These updates will bring KPD offer timelines into alignment with current practices, improving the efficiency of the OPTN KPDPP and potentially the match success rate.

### *OPTN KPDPP Match Offer and Exchange Deadlines*

The Committee proposes the following condensed match offer and exchange deadlines:

- The hospitals involved in the exchange must agree in writing upon the contents required in the crossmatch kit, instructions for the donor, and the addresses at which to send completed blood samples **within three business days, shortened from the current deadline of four business days**
- The hospitals involved in the exchange must report the agreed upon date of the crossmatch and make the matched donor's records accessible to the matched candidate's transplant hospital **within three business days, shortened from four business days**
- The candidate's transplant hospital must report to the OPTN results of the crossmatch, review the matched donor's records, and confirm acceptance or report a refusal of the match offer to the OPTN **within 10 business days, shortened from 15 business days**

Shortening exchange timelines will improve the efficiency of the OPTN KPDPP by aligning deadlines with current practices and information sharing capabilities and reducing the time from match offer to transplant.<sup>4,5</sup> The Workgroup considered shortening the deadline for preliminary match offer response and determined that the current two business days was still an appropriate timeframe, in consideration for smaller KPD programs with limited staffing.<sup>6</sup> Public comment feedback revealed support for these condensed timelines, as well as for maintaining a two business day preliminary response timeline.

The Committee also proposes two new deadlines in the OPTN KPDPP for paired donor recovery and candidate transplant, which do not exist in current policy:

- The matched candidate's transplant hospital and the matched donor's transplant hospital must agree upon a date and time for the recovery of the matched kidney **within 15 business days of receiving the match offer**
- The transplant hospitals participating in the exchange must schedule both the recovery of the kidney from one of the matched donors in the exchange and the subsequent transplant of their matched candidate to occur **within 60 calendar days of receiving the match offer**

The proposed deadline to agree upon a date and time for the recovery of the matched kidney came from community feedback recommending a timeline for which all programs in an exchange agree upon a scheduled surgery date. The KPD Workgroup considered this feedback and agreed that establishing a deadline for programs to agree upon a date and time for matched donor kidney recovery would increase

<sup>4</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, April 18, 2022. <https://optn.transplant.hrsa.gov/media/tcol2qx5/220220418-kpd-summary.pdf>

<sup>5</sup> OPTN Kidney Paired Donation Workgroup, Administrative Focus Group Meeting Summary, February 2, 2022. <https://optn.transplant.hrsa.gov/media/vxblcjij/20220202-kpd-administrative-focus-group-summary.pdf>

<sup>6</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022. <https://optn.transplant.hrsa.gov/media/aapn15jx/220220516-kpd-summary.pdf>

the efficiency of KPD exchanges. The Workgroup noted that such a deadline would encourage increased planning and communication between programs in order to finalize and schedule surgery dates<sup>7</sup>. After review of public comment feedback and at the recommendation of the OPTN KPD Workgroup, the Committee is proposing a deadline of 15 business days for this agreement.<sup>8</sup>

In regards to the 60 day timeframe from match offer to transplant and recovery, public comment feedback was generally supportive, with some commenters expressing concern for requiring surgeries to occur within a specific timeframe. Commenters noted concerns that a specific deadline to surgery may infringe on donor autonomy, and may be challenging for smaller programs. After considering this feedback, the Committee updated the policy language to emphasize that programs will be required to *schedule* the recovery and transplant *to occur* within 60 days from time of match offer.<sup>9</sup> These post-public comment changes are intended to balance improved efficiency in the OPTN KPDPP and patient and donor autonomy.

The shortened match offer and exchange deadlines, along with the proposed recovery and transplant deadlines, establish a more efficient timeframe for KPD exchanges and will potentially improve the success of the KPD program.<sup>10</sup> This will help reduce the time between match offer and transplant, which in turn reduces the risk of an exchange breaking due to issues such as candidate illness or donor unavailability.<sup>11,12</sup>

### *OPTN KPDPP Deadline Development Considerations*

The proposed deadline modifications were informed by experiential evidence of the Workgroup, which includes members from participant programs in the OPTN KPDPP, with feedback from both the OPTN Transplant Coordinators (TCC) and Transplant Administrators Committees (TAC). Members emphasized that longer times from match run to transplant increase the risk that a donor or candidate issue develops, such as pregnancy, loss of employment, health insurance changes, or illness, which can prevent the fulfillment of the chain or exchange.<sup>13</sup>

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<sup>7</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>8</sup> OPTN Kidney Transplantation Committee Meeting Summary, November 7, 2022

<sup>9</sup> Ibid.

<sup>10</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022.

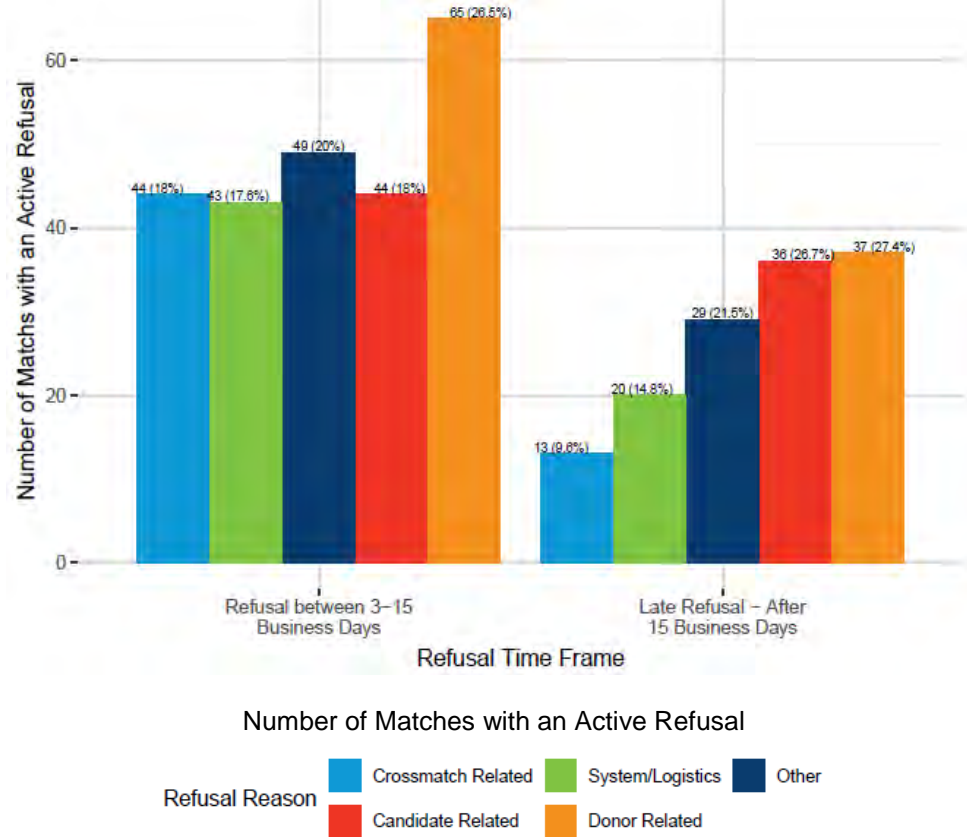
<sup>11</sup> OPTN Kidney Paired Donation Workgroup, Administrative Focus Group Meeting Summary, February 2, 2022.

<sup>12</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022. <https://optn.transplant.hrsa.gov/media/nakovbke/20220617-kpd-summary.pdf>

<sup>13</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022.

Match refusal data from 2016 through 2021 (**Figure 1**) supported these concerns; donor-related and candidate-related refusal reasons were the leading reasons for all match refusals submitted after 15 business days from time of match offer.<sup>14,15</sup>

**Figure 1: OPTN KPDP Match Offer Refusals by Time Frame of Refusal and Refusal Reason (2016-2021)**



Donor and candidate-related refusal categories include reasons such as:

- Patient illness, unavailability, or temporary unsuitability
- Candidate already transplanted, transplant in progress, or other offer being considered
- Candidate involved in pending exchange with another KPD program
- Donor unavailability, including donor pregnancy, donor travel, etc.
- Patient death

In a few cases, donors refused to donate on the exchange timeline, citing that the match timing was too long.<sup>16</sup>

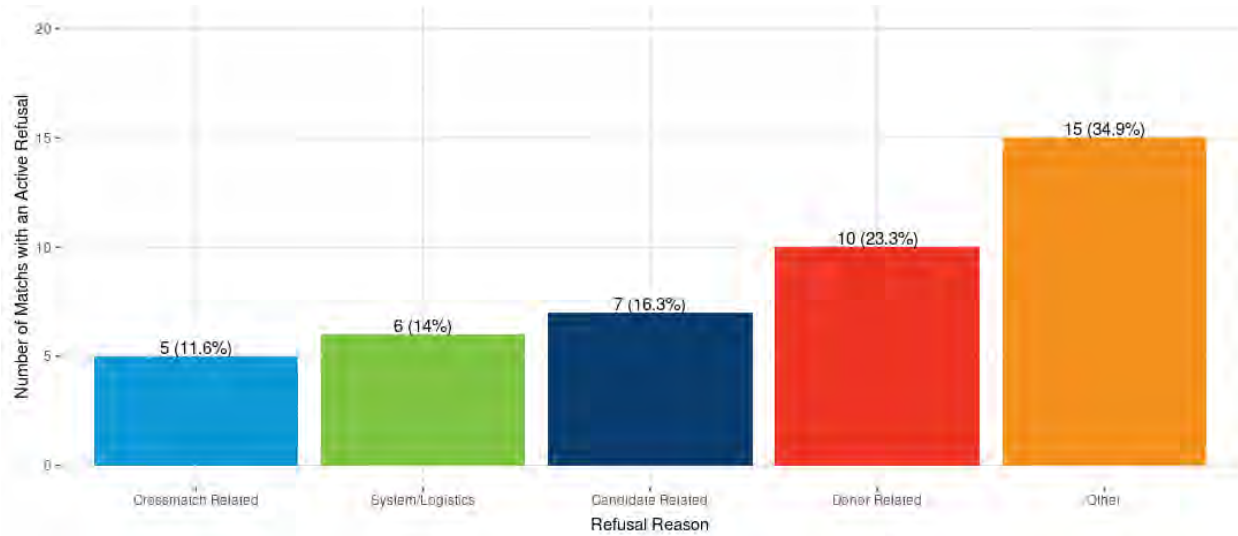
<sup>14</sup> Analysis of OPTN KPDP Match Refusal Data from 2016-2021, presented to the Workgroup on June 17, 2022.

<sup>15</sup> Between 2016 and the end of 2021, 25 percent of offers refused after the preliminary response deadline occurred at least 31 days from time of match offer, and 11 percent occurred 60 days or more from time of match offer.

<sup>16</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022.

Of note, systems and logistics-related refusal reasons remained relatively low, accounting for only 14 percent of all refusals submitted after 60 calendar days, as shown in **Figure 2**.<sup>17</sup>

**Figure 2: OPTN KPDPP Match Offer Refusals Submitted After 60 Calendar Days by Refusal Reason (2016 – 2021)**



After reviewing these data, the Workgroup achieved consensus in support of the condensed exchange deadlines and the proposed transplant and recovery deadlines, reiterating the reduced transplant and recovery timelines will reduce the risk of a match run failing due to donor and candidate issues as revealed in the data.<sup>18,19</sup> Furthermore, the low frequency of systems and logistics related refusal reasons after 60 days indicates that a 60 day timeframe between match offer and transplant and recovery should not pose logistical challenges to OPTN KPDPP programs. The Workgroup and members of the TCC and TAC also noted the OPTN KPDPP’s extension request process, which allows programs to request extended deadlines where necessary.<sup>20</sup>

### *Extension Request Policy*

Current policy regarding extension requests specifies that an extension request is automatically denied and the exchange terminated if any of the hospitals in the exchange fails to respond to the extension request within the allotted timeframe.<sup>21</sup> The Workgroup acknowledged that a hospital may not submit a response for any number of reasons, particularly smaller programs with limited KPD staff.<sup>22</sup> The Workgroup emphasized that termination of an exchange due to administrative process failures was unfair to the patients in the exchange, and recommended that a non-response by any transplant hospital in the exchange default to an approval of the extension request.<sup>23</sup> The Committee proposes modifying this policy, such that the extension is granted if any of the transplant hospitals in the

<sup>17</sup> Analysis of OPTN KPDPP Match Refusal Data from 2016-2021.

<sup>18</sup> Analysis of OPTN KPDPP Match Refusal Data from 2016-2021, presented to the Workgroup on June 17, 2022.

<sup>19</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022.

<sup>20</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022

<sup>21</sup> OPTN Policy 13.11.A: Requesting a Deadline Extension for a KPD Exchange

<sup>22</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022.

<sup>23</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, April 18, 2022.

exchange fail to respond. This update will prevent the termination of an exchange due to non-response and so prevent patients from being negatively impacted due to an administrative lapse.<sup>24</sup>

### *Match Offer Review Requirements*

The Workgroup also discussed the match offer review requirements, including required donor information sharing with the matched candidate’s transplant hospital. The Workgroup considered specifying certain donor information to be made available, particularly renal images. Renal images are critical to offer evaluation, as they provide necessary information regarding organ anatomy. The Workgroup also considered requiring renal images and other pertinent donor information to be made available upon offer receipt. The Workgroup noted that specifying required donor information could streamline donor information sharing.<sup>25</sup>

Public comment revealed support for standardizing and specifying required donor information, particularly noting benefits to streamlining offer review. The KPD Workgroup reviewed this feedback and will consider these recommendations for future policy development.<sup>26</sup>

## Informed Consent

The Committee proposes several modifications to informed consent policies for KPD participants, including *OPTN Policy 13.3: Informed Consent to KPD Candidates* and *OPTN Policy 13.4: Informed Consent for KPD Donors*. These updates will provide clarity on applicable patient populations and ensure appropriate, holistic informed consent. One such modification includes clarifying language in informed consent policies for KPD donors and candidates that these requirements apply to donors and candidates participating in any KPD program.

Current informed consent policy for KPD donors requires that transplant programs inform potential paired donors of “the possibility that the matched candidate’s insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital.” The Workgroup felt that this language was not inclusive enough of overall financial risk to living donation, and that financial risk conversations should also include education on potential resources available to defray costs related to living donation, such as the National Living Donor Assistance Center.<sup>27</sup> Though it is rare for paired donors to travel to the matched recipient, the Workgroup acknowledged the nuance of travel costs in regards to living donation in a KPD program.<sup>28</sup> The Committee proposes alignment of financial risk language for informed consent for KPD donors with that in *OPTN Living Donation Policy 14.3: Informed Consent Requirements*. This alignment expands informed consent requirements for KPD donors to be more inclusive of financial risks and to ensure KPD donors are informed of resources potentially available to mitigate donation related costs.<sup>29</sup>

The Committee also proposes a requirement that the transplant hospital obtain the paired donor’s signature confirming that the paired donor has been informed that they may withdraw from

<sup>24</sup> Ibid.

<sup>25</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, June 17, 2022.

<sup>26</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>27</sup> National Living Donor Assistance Center. <https://www.livingdonorassistance.org/>

<sup>28</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022.

<https://optn.transplant.hrsa.gov/media/y30g3sqs/20211213-kpd-meeting-summary.pdf>

<sup>29</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022



participation in the KPD program at any time, for any reason.<sup>30</sup> This update clarifies language regarding the paired donor's right to withdraw and aligns informed consent documentation requirements with those in *OPTN Living Donation Policy 14.3: Informed Consent Requirements*.<sup>31, 32</sup>

Public comment feedback was widely supportive of the proposed updates to informed consent requirements. There was particular support for increased transparency, emphasis on donor autonomy, and expanded financial risk language. There was also support for clarity in which policies are required for all KPD programs as opposed to the OPTN KPDPP. The Workgroup considered this feedback, and agreed that additional clarification may be needed. At the recommendation of the KPD Workgroup, the Committee opted to include additional policy language clarifications as a post-public comment change, to specify which policies apply to all KPD exchanges and which apply only to the OPTN KPDPP.<sup>33</sup>

## Bridge Donors

KPD Chains can be initiated by unpaired, non-directed living donors. In these cases, the candidate at the end of the chain is matched while their donor becomes an "Exchange Ending Donor." Exchange ending donors will either initiate a new KPD chain as a bridge donor in a future match run, donate to a candidate on the deceased donor waitlist, or refuse to donate. In discussing OPTN policies regarding bridge donors, the Workgroup found the current definition of bridge donor to be unclear and potentially confusing.<sup>34</sup> The Workgroup felt it was appropriate to update the definition of Bridge Donor as shown in *OPTN Policy 1.2: Definitions*, to reflect these options. After reviewing public comment feedback and further consideration, the Committee opted to adjust the proposed definition, for clarity and emphasis on donor autonomy.<sup>35</sup> The Committee proposes the following definition of Bridge Donor:

### **Bridge Donor**

A KPD donor at the end of a KPD chain who chooses to participate in future KPD match runs.

Currently, *OPTN Policy 13.4.E: Additional Requirements for Bridge Donors* imposes additional informed consent requirements for Bridge Donors, due to their unique circumstance. These requirements include providing an estimate of how long a bridge donor can expect to wait before undergoing surgery to recover their kidney, based on the experience of the transplant hospital. The bridge donor has the option to revise the amount of time they are willing to be a bridge donor based on this estimate, and the transplant hospital must maintain documentation of how long a bridge donor is willing to be a bridge donor. In discussing this requirement, the Workgroup noted that accurate estimates are difficult to obtain and can vary, particularly due to donor factors such as blood type and human leukocyte antigen (HLA) typing.<sup>36</sup> The Workgroup iterated that the most influential and important factor in how long a donor can expect to wait is how long the bridge donor is willing to wait.<sup>37</sup> Acknowledging this, the Committee proposes removing the requirement to provide an estimate, and instead including language emphasizing the bridge donor's autonomy in determining how long they are willing to wait. Transplant hospitals will still be required to document in the donor's medical record how long the donor is willing

<sup>30</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022

<sup>31</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, May 16, 2022

<sup>32</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022

<sup>33</sup> OPTN Kidney Transplantation Committee Meeting Summary, November 7, 2022

<sup>34</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022

<sup>35</sup> OPTN Kidney Transplantation Committee Meeting Summary, November 7, 2022

<sup>36</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022

<sup>37</sup> *Ibid.*

to be a bridge donor, and any revisions to how long the donor is willing to be a bridge donor. This policy will ensure both bridge donor autonomy and that the transplant program has explicit conversations with the bridge donor regarding expectations.<sup>38</sup>

The Workgroup discussed including a requirement for the transplant program to obtain the bridge donor's signature confirming that the bridge donor has been informed that they may determine how long they are willing to be a bridge donor, and that they may revise that estimate. Ultimately, the Workgroup determined that a signature would not necessarily be appropriate, as bridge donors may continue to revise how long they are willing to be a bridge donor.<sup>39</sup> Feedback from public comment was mixed regarding concept of requiring transplant programs to obtain a signature from the donor on their willingness to wait. Commenters expressed concerns that requiring a signature on a donor's estimated willingness to wait could be interpreted as a binding agreement, which would be counter intuitive to the concept of an ongoing and continuous informed consent conversation. The OPTN KPD Workgroup considered this feedback and agreed, opting not to require the bridge donor's signature confirming their informed consent.<sup>40</sup>

The public comment submitted by the OPTN Living Donor Committee included a recommendation to require transplant programs to inform bridge donors of all of the options available to them. At the recommendation of the OPTN KPD Workgroup, the Kidney Committee is incorporating this feedback as a post-public comment change, and proposing a requirement for transplant programs to inform bridge donors of all of the bridge donor's options for donation, as well as their right to decline to donate at any time, for any reason.<sup>41,42</sup> This update will encourage increased transparency and expand informed consent for bridge donors in any KPD program.<sup>43</sup>

## Additional Clarifications and Alignments

The Committee proposes modifications to non-directed donor requirements in both KPD and Living Donor policy. These modifications include minor updates to *OPTN Policy 13.4.D: Additional Requirements for Non-Directed Donors*, to specify these requirements apply to non-directed donor participants in any KPD program and to remove reference to the donor's donation service area, which is no longer relevant.<sup>44</sup>

Previously, the Committee proposed the inclusion of a cross reference in *OPTN Policy 14.6.B: Placement of Non-Directed Living Donor Organs*, which notes these requirements do not apply to non-directed donors participating in a KPD program. The cross reference was meant to clarify that non-directed living kidney donors participating in a KPD program are subject to *OPTN Policy 13.4.D: Additional Requirements for Non-Directed Donors*.<sup>45</sup> After more discussion and review of public comment feedback, the Committee determined that this reference was unnecessary. The Committee noted that this reference may create additional confusion, as the intent of *OPTN Policy 14.6.B: Placement of Non-*

<sup>38</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, February 28, 2022. <https://optn.transplant.hrsa.gov/media/bbkbm4wd/20220228-kpd-summary.pdf>

<sup>39</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, February 28, 2022. <https://optn.transplant.hrsa.gov/media/bbkbm4wd/20220228-kpd-summary.pdf>

<sup>40</sup> Ibid.

<sup>41</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>42</sup> OPTN Kidney Transplantation Committee Meeting Summary, November 7, 2022

<sup>43</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>44</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, April 18, 2022.

<sup>45</sup> OPTN Kidney Paired Donation Workgroup, Informed Consent Focus Group Meeting Summary, January 31, 2022.

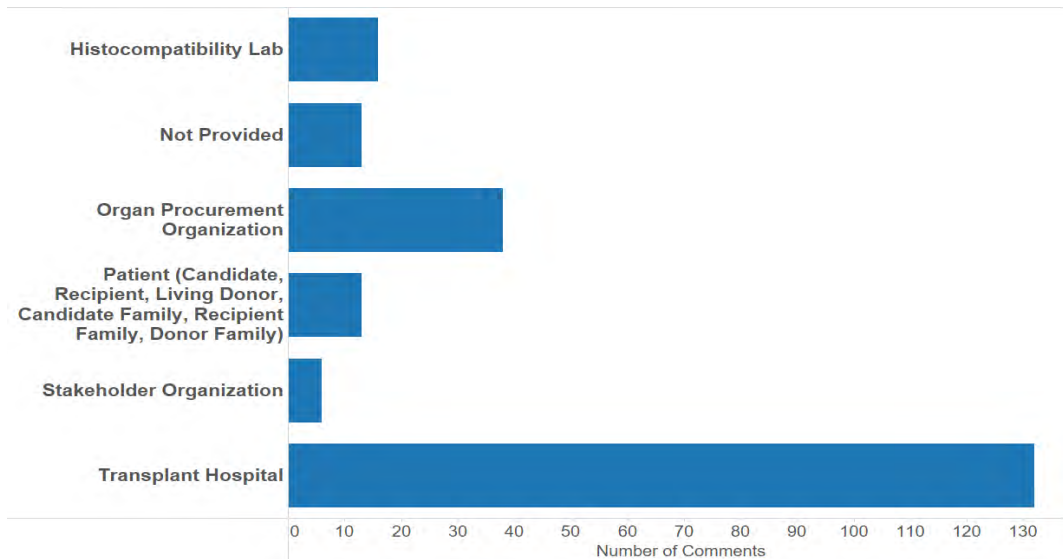
*Directed Living Donor Organs* relates to how non-KPD non-directed donor organs are allocation, while the referenced *OPTN Policy 13.4.D: Additional Requirements for Non-Directed Donors* relates to informed consent requirements for non-directed donors participating in a KPD exchange.<sup>46</sup> The Committee is no longer proposing this cross-reference.

The Committee also proposes minor language updates to *OPTN Policy 13.7.G: OPTN KPD Waiting Time Reinstatement*, to align with general OPTN policy regarding immediate and permanent non-function of a transplanted kidney.<sup>47</sup>

## Overall Sentiment from Public Comment

This proposal was presented to two other OPTN Committees during the Public Comment period for feedback, and a video presentation describing the proposal was posted the OPTN website. While this proposal was not presented at OPTN regional meetings, community representatives were able to submit sentiment and written comment on this proposal at each regional meeting. Six professional organizations as well as a number of transplant programs and individuals provided written public comment. The transplant and donation community was generally supportive of this proposal, though a number of comments recommended minor language updates to proposed policy language, particularly regarding match offer response and coordination time frames. The proposal collected sentiment from 207 respondents, including 21 written comments, about 10 percent of all responses. Sentiment is detailed below in **Figures 3-5**:

**Figure 3: Volume of Comments by Member Type, Update KPD Policy Proposal, 2022**

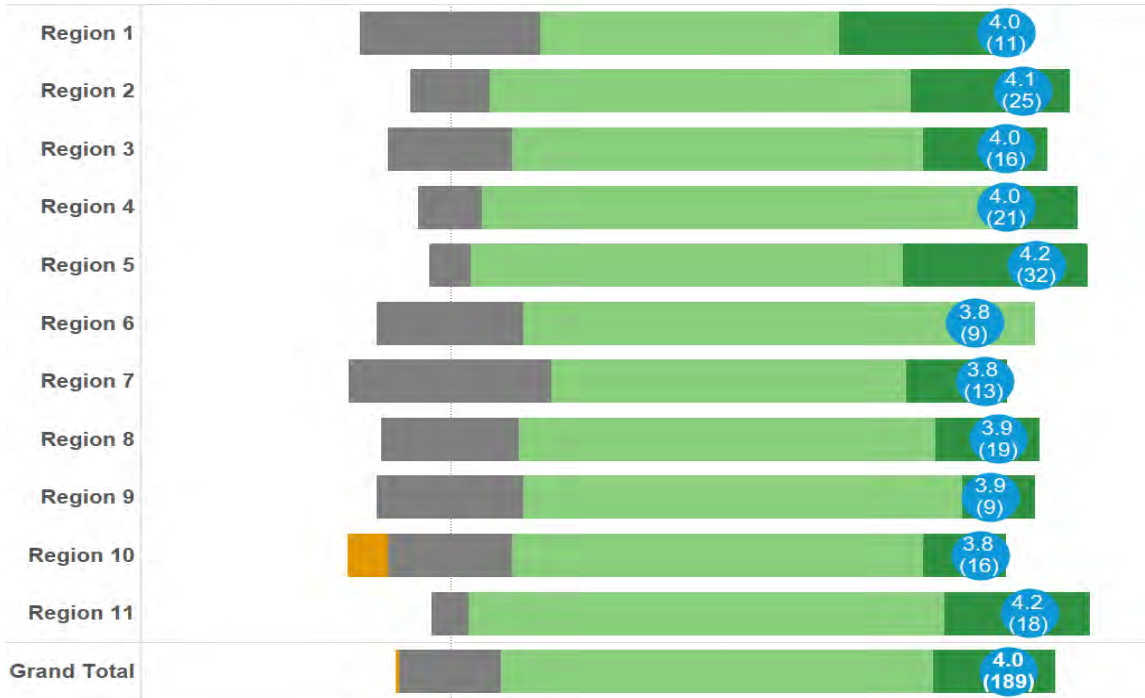


The comments received represent all member types, with the greatest participation coming from transplant programs.

<sup>46</sup> OPTN Kidney Transplantation Committee Meeting Summary, November 7, 2022

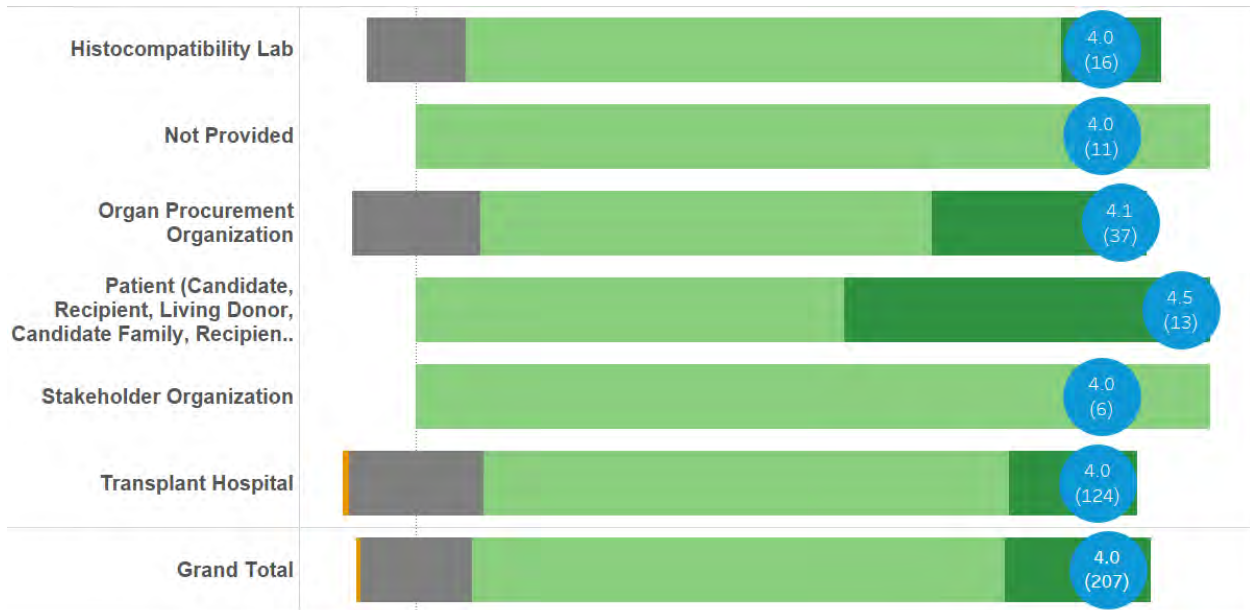
<sup>47</sup> OPTN Kidney Paired Donation Workgroup, Administrative Focus Group Meeting Summary, February 2, 2022.

**Figure 4: Regional Sentiment, Update KPD Policy Proposal, 2022**



There was support for the proposal across all eleven regions, though there was one respondent in Region 10 who indicated opposition, based on concerns for potential administrative burden.

**Figure 5: Sentiment by Member Type, Update KPD Policy Proposal, 2022**



There was support for this proposal across member types, with opposition indicated only by transplant hospital members.

Public comment feedback covered many topics, including:

- General support for establishing shorter, more efficient OPTN KPDPP offer timelines, with some concerns for administrative burden among smaller centers
- Overall support for updates to informed consent policies, including emphasis on donor autonomy and transparency for patients and related recommendations
- Recommendations on future policy developments regarding donor information sharing and extension request policies.

## OPTN KPDPP Match Offer and Exchange Deadlines

Submitted comments expressed support for reduced timeframes and increased efficiency, as well as mitigating the potential for delays to an exchange. There was some concern for administrative burden, and smaller programs’ ability to meet proposed deadlines. One commenter noted that “strict timeline could have unintended consequences when dealing with multiple centers, multiple donors and recipients, surgical and OR scheduling restrictions, etc.” The NKF recommended that the OPTN to continue to engage with smaller programs to aide in adhering to these deadlines.

Commenters supported maintaining the two business day preliminary response deadline, noting that this provided sufficient time for programs to adequately review and respond. Members emphasized that two business days was an appropriate timeframe for smaller programs. The KPD Workgroup considered

this feedback and recommended that the Kidney Committee maintain the two business day preliminary response deadline.<sup>48</sup>

Many comments supported establishing a 60 day timeframe from match offer to transplant and recovery. Some commenters did note that 60 days is a long time, and may still leave room for something to occur that prevents the exchange from occurring. The American Society of Transplant Surgeons noted that smaller or rural programs may have issues with OR availability, and will need to respond by only entering donors into KPDPP if they are ready to go to surgery. Respondents shared concerns for requiring surgeries to occur within a specific timeframe within the policy language, noting concerns that a specific deadline to surgery could infringe on donor autonomy, and that such a requirement could be interpreted as an element of pressure for potential donors. Others expressed concern for the stringency of the deadline, noting that sudden operating room or surgeon unavailability could require programs to move recovery or transplant dates beyond the 60 day deadline.

Commenters submitted several recommendations to address these concerns, including softening the language around the 60 day match offer to transplant requirement. The Workgroup also supported updating the proposed policy language around deadlines to transplant and recovery to balance efficiency and patient autonomy. After reviewing public comment feedback and the Workgroup's recommendation, the Kidney Transplantation Committee opted to require matched transplant hospitals to schedule the recovery and transplants to occur within 60 days of receiving the match offer.

Feedback provided by the OPTN Transplant Coordinators Committee also included a suggestion for a deadline requiring all programs within an exchange to agree upon a surgery date within 30 calendar days. The OPTN KPD Workgroup considered this feedback, and supported the inclusion of a deadline for programs in an exchange to agree upon a date for recovery, noting that this could improve exchange efficiency by encouraging increased and early planning and communication between transplant programs. The Workgroup agreed that a 15 business day deadline for programs to agree upon a surgery date was appropriate, allowing transplant hospitals an appropriate amount of time to coordinate after their final acceptance and before the planned surgeries.<sup>49,50</sup> After reviewing public comment feedback and the Workgroup's recommendation, the Committee opted to incorporate the following deadline as a post-public comment change:

- The match candidate's transplant hospital and matched donor's transplant hospital must agree upon a date and time for the recovery of the matched donor kidney(s) **within 15 business days from time of match offer.**

The Kidney Committee also opted to include an additional reference to the extension request policy within *Policy 13.11: Receiving and Accepting KPD Match Offers*, to emphasize the extension pathway is available, particularly if a donor is unavailable to donate within the timeframes established in OPTN Policy.

## Informed Consent: Transparency and Patient Communication

There was support for expanded language regarding financial risk and improved clarity in informed consent policies, including support for increased transparency and communication to patients. The ASTS

<sup>48</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>49</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>50</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.

noted that the proposed “timeframe will also implicitly increase communication between donor and donor recovery hospital.”

The NKF expressed support for increased transparency and clarity in patient communication and informed consent, noting particularly support for requiring a signature from donors demonstrating their awareness that they may decline to participate as a living donor, the inclusion of financial risk in informed consent, and emphasis on donor autonomy.

## Bridge Donors and Donor Autonomy

Public Comment revealed support for increased emphasis on donor autonomy, as well as increased communication and patient understanding. There was support for allowing donors to make a determination on their own willingness to wait and to revise their own estimates as necessary, rather than requiring a timeframe for willingness to be a bridge donor.

Public comment feedback was mixed regarding concept of requiring transplant programs to obtain a signature from the donor on their willingness to wait. While one commenter supported obtaining a signature, many other expressed concerns, including that requiring a signature could be counter intuitive to the concept of an ongoing and continuous conversation about informed consent. Commenters noted that requiring a signature on a donor’s estimated willingness to wait could be interpreted as a binding agreement. The OPTN KPD Workgroup considered this feedback and agreed, opting to require only that transplant programs maintain documentation of this ongoing discussion and any revisions to the donor’s estimated period of willingness to wait.<sup>51</sup>

The OPTN Living Donor Committee recommended that policy be updated to clearly state all of the donation options available to a bridge donor. The Workgroup agreed with this recommendation, and incorporated a requirement for transplant programs to inform the bridge donor of their right to decline to donate at any time, for any reason, and of all of their options for donation.<sup>52</sup>

## Program Performance and Extension Request Policy

As previously mentioned, public comment largely supported the condensed match offer deadlines, with commenters noting that proposed updates will improve efficiency, increase the aggressiveness of the OPTN KPDPP, and encourage increased participation. The ASTS recommended that KPDPP policies avoid becoming overly prescriptive, at the risk of dis-incentivizing participation. The Committee and the KPD Workgroup discussed this feedback, and will consider this recommendation with future policy development.

Commenters were supportive of the proposed updates to the extension request policy, particularly emphasizing the increased fairness to patients. The Committee sought feedback throughout public comment on ways to reduce over-use of the extension request policy, or use of extensions in less than extenuating circumstances. The AST suggested specifying a maximum duration for each extension, as well as a maximum number of extension requests that a program may submit. The AST also recommended that programs only register candidate and donor pairs after complete evaluation. The OPTN Transplant Coordinators Committee suggested that requiring programs to provide a reason for

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<sup>51</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 18, 2022.

<sup>52</sup> Ibid.

extension requests could both discourage over use of extension requests and allow for requests to be tracked and evaluated. The OPTN KPD Workgroup considered this feedback, and noted that OPTN KPD Policy already requires transplant programs to have completed the potential KPD donor’s evaluation before the donor is eligible to participate in match runs, and that programs are also required to describe the reason for their extension request.<sup>53,54</sup>

## Donor Information Sharing

Public comment revealed support for standardizing clinical kidney paired donor information necessary for evaluation, as well as for requiring a donor’s renal imaging to be shared and available to the matched candidate’s transplant hospital to review. Commenters recommended establishing a requirement for patients to maintain updated testing while active in the KPD registry, which would require active pairs to be clinically ready and suitable for transplantation and donation. NATCO submitted a recommendation to make clinical donor information and evaluation records available at time a preliminary offer was submitted, noting that this would streamline offer review. The KPD Workgroup discussed this feedback and is considering these recommendations for future policy development.<sup>55</sup>

## Compliance Analysis

### NOTA and OPTN Final Rule

In 2006, the Department of Health and Human Services (HHS) directed the OPTN to exercise oversight over living donation.<sup>56</sup> Under 42 CFR 121.4(a)(6), the Secretary directed the OPTN “to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule.”<sup>57</sup> Furthermore, Congress modified NOTA in 2007 to permit human organ paired donation under the law,<sup>58</sup> and the current OPTN Contract requires the Contractor to “maintain KPDP policies and develop new policies.”<sup>59</sup> This project addresses living organ donors and candidates enrolled in kidney paired donation programs, including the KPDP, by updating kidney-paired donation policy.

### OPTN Strategic Plan

This proposal aligns with the strategic goal to increase the number of transplants. These updates will improve the efficiency of the OPTN KPD pilot program and clarify informed consent requirements. These updates to efficiency will reduce the amount of time from match offer to transplant and reduce the risk that the exchange or chain will break due to donor or candidate issues. This will help increase the success of KPD exchanges, and so increase the number of transplants.

<sup>53</sup> OPTN Policy 13.6.B (3): Requirements for Match Run Eligibility for Potential KPD Donors

<sup>54</sup> OPTN Policy 13.11.A: Request a Deadline Extension for a KPD Exchange

<sup>55</sup> OPTN Kidney Paired Donation Workgroup Meeting Summary, October 5, 2022.

<sup>56</sup> Department of Health and Human Services, Health Resources and Services Administration, “Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines,” 71 Fed. Reg. 34946 No. 116 (June 16, 2006).

<https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-and-transplantation-network-optn-living-donor> (accessed June 23, 2020).

<sup>57</sup> Ibid.

<sup>58</sup> 42 USC §274e

<sup>59</sup> Organ Procurement and Transplantation Network; HSH250201900001C, Performance Work Statement Task 3.4.3: Operate the OPTN Kidney Paired Donation Pilot Project (KPDP)



## Implementation Considerations

### Member and OPTN Operations

#### *Operations affecting Transplant Hospitals*

This proposal is expected to impact transplant program participants in the OPTN KPDPP. Participating transplant programs will need to coordinate with staff to ensure match offer review requirements are completed within the updated deadlines. Participating transplant programs will also need to coordinate and organize with each other to ensure the proposed recovery and transplantation deadlines are met.

This proposal also includes updates to informed consent requirements. Transplant programs participating in any KPD program will need to ensure their candidates and living donors are appropriately consented and appropriate documentation maintained.

#### *Operations affecting Histocompatibility Laboratories*

This proposal shortens deadlines related to crossmatching and reporting crossmatching results. This is expected to have minimal impact on Histocompatibility Laboratories, who will need to ensure typing materials are processed and cross-matched in a timely manner.

#### *Operations affecting Organ Procurement Organizations*

This proposal is not anticipated to affect the operations of organ procurement organizations.

#### *Operations affecting the OPTN*

This proposal will not require information technology implementation. OPTN Policy will be updated, and a policy notice sent out to members. Current educational offerings for participating transplant programs will be updated appropriately.

## Potential Impact on Select Patient Populations

The expanded and clarified informed consent requirements will positively impact living kidney donor and kidney candidate participants in all KPD programs, with expanded and clarified informed consent requirements. The requirement to inform living donor participants in KPD programs of potential resources available to defray donation-related costs, as well as expanded specification of financial risk, will particularly benefit living donor participants in all KPD program. The proposed policy changes will have the greatest positive impact on participants in the OPTN KPDPP, who will benefit from improvements to the overall efficiency of the program, due to shortened match offer review deadlines and the addition of deadlines for match offer to transplant and recovery. Participants in the OPTN KPDPP will also benefit from updates to the exception request policy, which prevent the termination of an exchange due to administrative lapse.

## Projected Fiscal Impact

### *Projected Impact on Histocompatibility Laboratories*

There is expected to be minimal fiscal impact for histocompatibility laboratories, mainly related to training, and no expected ongoing costs.

### *Projected Impact on Transplant Hospitals*

There is no expected fiscal impact for transplant hospitals.

### *Projected Impact on the OPTN*

This proposal will not require any information technology changes, but will involve standard educational and communication efforts.

### *Projected Impact on Organ Procurement Organizations*

There is no expected fiscal impact for organ procurement organizations.

## Post-implementation Monitoring

### Member Compliance

The OPTN will continue to review the KPD requirements as outlined in policy. Site surveyors will also review a sample of KPD donor medical records for a document signed by the paired donor confirming that the paired donor has been informed that the paired donor may withdraw from participation in the KPD program at any time, for any reason.

### Policy Evaluation

This policy will be formally evaluated approximately 1 year and 2 years post implementation. The following metrics will be evaluated as OPTN KPDP data become available and compare pre- and post-policy implementation cohorts:

- Median time from match run to transplant
- Numbers and percentages of initially accepted match offers that requested an extension of deadlines for evaluations post-match outlined in policy proposal *Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer*
- Count of reasons for requested extension of deadlines for evaluations post-match outlined in policy proposal *Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer*

## Conclusion

The OPTN Kidney Transplantation Committee proposes a series of minor modifications to OPTN KPD policy to provide clarity, align policy language with other OPTN policies, and improve efficiency of the KPD program.

The proposed modifications will condense match offer and evaluation deadlines, bringing them up to date with current practices. This will shorten the time between match offer and transplant, which in turn will reduce the risk of chain breakage due to issues such as candidate illness or donor unavailability. Additional adjustments to administrative policies are proposed, to prevent termination of exchanges due to administrative lapses. At the recommendation of the OPTN KPD Workgroup, the Committee is incorporating an additional deadline for programs participating in the exchange to agree upon a date and time for the recovery of the matched donor kidney(s). This additional deadline will encourage increased efficiency in the OPTN KPDPP, help reduce time between match offer and transplant, and so may improve the match success rate. The Committee is also making minor language changes for the deadlines to recovery and transplant, to balance efficiency and emphasis on donor autonomy.

The Committee also proposes updates to several informed consent policies for both candidate and donor KPD participants, to provide clarity, emphasize donor autonomy, and align requirements with those in OPTN Living Donor Policy. These changes include expanded language regarding financial risk and potential resources available to defray donation related costs. Informed consent requirements for bridge donors will also be modified, to underscore donor autonomy in determining how long a bridge donor is willing to wait and ensure transplant programs maintain documentation of donor decisions. After reviewing public comment feedback, the Committee is incorporating additional minor language clarifications and a requirement for transplant programs to inform bridge donors of their right to decline to donate at any time, for any reason, and of all of their options for donation.

## Proposed Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 1.2 Definitions

#### 2 **Bridge donor**

3 A Kidney Paired Donation (KPD) donor ~~who does not have a match identified during the same match run~~  
4 ~~as the donor's paired candidate and continues a chain in a future match run~~ at the end of a KPD Chain  
5 who chooses to participate in future KPD match runs.

### 7 13.3 Informed Consent for KPD Candidates

8 The below requirements apply to candidates participating in any KPD program, unless otherwise  
9 specified. (Leads into subsections)

10

### 11 13.4 Informed Consent for KPD Donors

12 The below requirements apply to donors participating in any KPD program, unless otherwise specified.  
13 (Leads into subsections)

14

#### 15 13.4.C *Additional Requirements for KPD Donors*

16 For any KPD exchange, the paired donor's transplant hospital must maintain documentation in  
17 the paired donor's medical record that it has informed the paired donor of *all* of the following:

18

- 19 1. The KPD program's matching requirements
- 20 2. KPD donors and candidates do not choose their match
- 21 3. A KPD donor or a candidate may decline a match
- 22 4. The possibility of helping more than one candidate receive a transplant
- 23 5. The possibility that the paired donor may have to wait to find a match
- 24 6. The possibility that the paired donor might have to wait longer to donate after a match has  
25 been identified because of logistical issues
- 26 7. The possibility that the paired candidate might not receive a transplant because of an  
27 unexpected issue with the matched donor's kidney found during or after surgery
- 28 8. The possibility that the paired donor's kidney might not be transplanted or the paired  
29 donor's matched candidate might not receive a transplant because of unexpected events
- 30 9. The KPD program's remedy for failed KPD exchanges and that the remedy does not include  
31 any additional priority for the paired candidate on the deceased donor waiting list
- 32 10. ~~The possibility that the matched candidate's insurance might not cover travel costs if the~~  
33 ~~paired donor travels to the matched recipient transplant hospital~~
- 34 11. The possibility that personal expenses of travel, housing, child care costs, and lost wages  
35 related to donation might not be reimbursed; however, resources might be available to  
36 defray some donation related costs.
- 37 12. The possibility that the paired donor's paired recipient and the paired donor's matched  
38 recipient might not have equal outcomes

- 39 13. The possibility of the paired donor’s name appearing on the matched candidate’s insurance
- 40 estimation of benefits
- 41 14. That the donor’s kidney could be lost in transport, and other potentially negative
- 42 consequences related to shipping a kidney
- 43 15. That the paired donor may require additional testing, including multiple blood draws for
- 44 crossmatching
- 45 16. The KPD program’s rules for when members are allowed to facilitate meetings between
- 46 matched donors and recipients
- 47

48 The paired donor’s transplant hospital must obtain the paired donor’s signature that confirms  
 49 the donor has been informed that the paired donor may of the right to withdraw from  
 50 participation in the KPD program at any time, for any reason.

51

52 **13.4.D Additional Requirements for Non-Directed Donors (NDD) Participants in KPD**  
 53 **Programs**

54 For any KPD exchange, before a NDD can participate in the KPD program, the NDD’s transplant  
 55 hospital must document in the NDD’s medical record that it has informed the NDD of all their  
 56 donation options including:

- 57
- 58 1. Participating in KPD
- 59 2. Donating to a candidate waiting for a deceased donor kidney according to *Policy 14.6.B:*  
 60 *Placement of Non-directed Living Donor Organs*
- 61 3. Any other options available ~~in the NDD’s donation service area~~ to the NDD
- 62

63 **13.4.E Additional Requirements for Bridge Donors**

64 For any KPD exchange, before a bridge donor is entered into a KPD match run, the bridge  
 65 donor’s transplant hospital is responsible for obtaining and maintaining documentation in the  
 66 donor’s medical record that it has informed the bridge donor of all the following:

- 67
- 68 1. The bridge donor may need to have another medical evaluation at a future time.
- 69 2. The bridge donor may need to be available to provide blood on multiple occasions for
- 70 crossmatching.
- 71 3. How the KPD program determines whether a chain ends with a bridge donor
- 72 4. The bridge donor may decline to donate at any time, for any reason
- 73 5. All of the bridge donor’s options for donation, including:
  - 74 a. Continued participation as a bridge donor in the KPD program
  - 75 b. Donation to a candidate waiting for a deceased donor kidney
  - 76 c. Any other options available to the bridge donor
- 77 6. ~~Approximately how long the bridge donor can expect to wait before undergoing surgery to~~  
 78 ~~recover the bridge donor’s kidney, based on the experience of the bridge donor’s transplant~~  
 79 ~~hospital. The bridge donor will have the option to revise the estimated amount of time the~~  
 80 ~~donor is willing be a bridge donor based on this information. The bridge donor determines~~  
 81 ~~the amount of time the donor is willing to be a bridge donor.~~ The bridge donor’s transplant  
 82 hospital will document in the donor’s medical record how long the donor is willing to be a

83 bridge donor. If the bridge donor revises the amount of time the donor is willing to be a  
 84 bridge donor, the bridge donor’s transplant hospital must document that revision in the  
 85 donor’s medical record.

86  
 87 The bridge donor’s transplant hospital must maintain documentation in the donor’s medical  
 88 record that the donor has verbally consented to remain a bridge donor each time the donor is  
 89 identified as a bridge donor in an accepted KPD exchange.

91 **13.7.G OPTN KPD Waiting Time Reinstatement**

92 KPD waiting time begins on the day the candidate’s transplant hospital registers the candidate in  
 93 the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is  
 94 registered in the OPTN KPD program. A candidate will accrue KPD waiting time at both active  
 95 and inactive status in the OPTN KPD program.

96 The OPTN will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN  
 97 KPD candidate experiences immediate and permanent non-function of any transplanted kidney  
 98 and the KPD candidate is re-registered in the OPTN KPD program with another living donor.  
 99 Immediate and permanent non-function of a transplanted kidney is defined as *either*:

- 100 1. Kidney graft removal within the first 90 days of transplant documented by a report of the
- 101 removal of the transplanted kidney.
- 102 2. Kidney graft failure within the first 90 days of transplant with documentation that the
- 103 candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated
- 104 glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days of the kidney
- 105 after the candidate’s kidney transplant.

106  
 107 KPD waiting time will be reinstated when the OPTN receives a request for reinstatement of KPD  
 108 waiting time and the required supporting documentation from the KPD candidate’s transplant  
 109 hospital.

110 **13.11 ~~Receiving and Accepting KPD Match Offers~~ KPD Match Offer and**  
 111 **Transplant Timing Requirements**

112 Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

113  
 114 **Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer**

The following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report to the OPTN a preliminary response	2 business days of receiving the match offer.
The matched candidate’s transplant hospital and the matched donor’s transplant hospital	Agree in writing upon all of the following: <ul style="list-style-type: none"> <li>• Contents required in the crossmatch kit</li> <li>• Instructions for the donor</li> <li>• Address at which to send the</li> </ul>	4 <u>3</u> business days of receiving the match offer.

The following members:	Must:	Within:
	completed blood samples	
The matched donor's transplant hospital	Report to the OPTN the agreed upon date of the crossmatch	<del>4</del> <u>3</u> business days of receiving the match offer.
The matched donor's transplant hospital	<p>Make all of the following matched donor's records accessible to the matched candidate's transplant hospital:</p> <ul style="list-style-type: none"> <li>Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital</li> <li>Whether the matched donor has any risk criteria for acute HIV, HBV, or HCV infection according to the <i>U.S. Public Health Service (PHS) Guideline</i></li> <li>Additional records requested by the matched candidate's transplant hospital</li> </ul>	<del>4</del> <u>3</u> business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN the results of the crossmatch	<del>15</del> <u>10</u> business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN	<del>15</del> <u>10</u> business days of receiving the match offer.
<u>The matched candidate's transplant hospital and the matched donor's transplant hospital</u>	<u>Agree upon a date and time for the recovery of the matched kidney(s)</u>	<u>15 business days of receiving the match offer</u>
<u>The matched donor's transplant hospital and matched candidate's transplant hospital</u>	<u>Schedule both the recovery of the kidney from one of the matched donors in the exchange and the subsequent transplant of their matched candidate to occur</u>	<u>60 days of receiving the match offer</u>

115  
116  
117  
118  
119  
120

If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines above, then the exchange will be terminated unless a transplant hospital requests an extension. If a transplant hospital submits an extension request before the deadline, the exchange will not terminate until the resolution of the extension request or the deadline is reached, whichever comes last.

### 121 13.11.A Requesting a Deadline Extension for a KPD Exchange

122 The transplant hospital may request an extension for any of the deadlines in *Table 13-4* by  
123 submitting a request in writing to the OPTN. This written request must include the reason for

124 the request and the new requested deadline date. Upon receipt of the request for extension,  
125 the OPTN will notify all of the transplant hospitals in the exchange. Upon notification, the  
126 transplant hospitals in the exchange must respond to the request for extension within 2  
127 business days. If all other transplant hospitals in the exchange agree to the extension, it will be  
128 granted. If any of the transplant hospitals in the exchange refuse the extension request, the  
129 extension will not be granted.

130

131 The transplant hospitals will have two business days to respond to the extension request. At  
132 the end of the first business day, the OPTN will send a second notification to any transplant  
133 hospital that has not yet responded. If any of the transplant hospitals fail to respond to the  
134 extension request at the end of the second business day, the extension ~~will not be granted and~~  
135 ~~the exchange will be terminated~~ will be granted.

#