OPTN

Request for Feedback

Concepts for Modifying Multi-Organ Policies

OPTN Ad Hoc Multi-Organ Transplantation Committee

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Concepts for Modifying Multi-Organ Policies

Sponsoring Committee: *Ad Hoc Multi-Organ Transplantation*
Public Comment Period: *January 23, 2024 – March 19, 2024*

Executive Summary

From January – March 2023, the Ad Hoc Multi-Organ Transplantation Committee (Committee) requested feedback on the concept paper *Identify Priority Shares in Kidney-Multi-Organ Allocation*.[1] The concept paper was the first step in a project that aims to improve equity in access to transplant between kidney-alone and kidney multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor. The Committee has been reviewing public comment feedback, evaluating data, and requests additional input on these topics. The purpose of this request for feedback is to gather additional community input on prioritization of single kidney candidates compared to multi-organ candidates, as well as policy guidance for general multi-organ (MOT) allocation.

The Committee requests feedback on all aspects of this paper, including the following questions:

MOT vs. Single Kidney Offers

- Do patients and donor family members support efforts to improve access to transplant for kidney candidates, even if it means that candidates registered for multiple organs may need to wait longer for a suitable donor?
- Should kidney-pancreas candidates be considered multi-organ candidates?
- When both kidneys are available from a donor with a KDPI between 0-34 percent:
    - Should one kidney be allocated to MOT (including KP), second kidney to kidney alone?
    - Should one kidney be allocated to MOT, second kidney to KP or kidney alone?
    - What are the potential impacts to KP and pediatric candidates?
- How should MOT candidates be prioritized when there is only one kidney available?

Policy Guidance for OPOs

- Should policy direct the order in which OPOs allocate organs? If so, how should expected waitlist mortality or graft survival be incorporated into the prioritization of candidates across different match runs?
- What additional policy or system considerations would OPOs need to follow a match run order directed by policy?
- Do patients and donor family members support efforts to promote more consistency in how organ allocation is managed by OPOs across the country?

[1] https://optn.transplant.hrsa.gov/media/mc0hfxrg/priority-shares-in-kidney-mot_concept_pc-winter-2023.pdf

Background

OPTN policies have historically required organ procurement organizations (OPOs) to allocate multiple organs from the same donor to multi-organ (MOT) candidates meeting certain criteria, prior to allocating individual organs to single organ candidates. The intent of these policies is to promote access to transplant for candidates experiencing failure in multiple organs, since (1) it can be harder for candidates to find a good match with two or more organs from the same donor, and (2) receiving organs from the same donor instead of from different donors may reduce the level of the candidate's immune system response and lower the risk that their body will reject the organs. [2,3] However, given the scarcity of organs, allocating more than one organ to a single candidate must be weighed against the opportunity to allocate lifesaving organs to multiple potential transplant recipients. Such equity concerns must also be balanced against considerations for efficient allocation of multiple organ types from one donor.

The 2023 *Identify Priority Shares in Kidney-Multi-Organ Allocation* Concept Paper requested community input on:

- If and when kidneys should be offered to kidney-alone candidates prior to kidney multi-organ candidates
- How to determine which kidney (including laterality) should be offered to various kidney multi-organ and single organ candidates, many of whom have equal priority for offers in current policy
- How to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by policy
- Providing more direction for multi-organ allocation while leaving flexibility for the dynamics of the allocation process

The majority of the feedback received from the community focused on promoting priority for specific groups relative to kidney MOT candidates. These specific groups include pediatric candidates, high Calculate Panel-Reactive Antibody (CPRA) candidates, medically urgent kidney-alone candidates, and prior living donors. The community also provided feedback regarding the MOT status of kidney with pancreas candidates, and the need for better guidance for OPOs during MOT allocation. Finally, the concept of designating one kidney for MOT and the other for kidney-alone transplantation from the same donor garnered support from a large portion of the community.

Project Plan

As outlined in the 2023 concept paper, the Committee is working on a project to establish an updated framework for kidney multi-organ allocation to improve equity in access to transplant between kidney-alone and kidney multi-organ candidates, and to improve efficiency in allocating multiple organ types

[2] Donation rates vary by organ and are highest for kidneys, followed by liver, heart, lung, and pancreas, which means that some donors will not be able to donate all of the organs that a multi-organ candidate needs. See OPTN/SRTR 2020 Annual Data Report. Published 2022. Accessed December 2, 2022. http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx. For donors that are able to donate multiple organs, there may be other organ-specific reasons why one of the organs would not be a good match for a certain multi-organ candidate, e.g., biopsy results unacceptable or organ anatomical damage or defect. See "Update to Refusal Codes," OPTN, Notice of Changes to OPTN Data Collection, accessed December 2, 2022, https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf.

[3] Receiving an organ transplant is a risk factor for sensitization. Candidates who are sensitized cannot accept donor organs with certain antigens due to the risk of morbidity and mortality. See Sarah Abbes, Ara Metjian, Alice Gray et al., "HLA sensitization in solid organ transplantation: a primer on terminology, testing, and clinical significance for the apheresis practitioner," *Therapeutic Apheresis and Dialysis* 21 no. 5 (2017): 441-450, DOI: 10.1111/1744-9987.12570.

from one donor. The Committee also aims to provide clarity for OPOs on how to proceed with MOT allocation, via policy direction or guidance.

Progress So Far

Since the release of the 2023 concept paper, the Committee has been evaluating public comment feedback and data to develop recommendations for a new MOT framework. The Committee's discussions have primarily been focused on kidney priority shares and MOT allocation efficiency and guidance.

MOT vs. Single Kidney Offers

The 2023 concept paper solicited feedback on how to allocate kidneys between single-organ and multi-organ candidates, and how to identify priority shares for kidney-alone candidates. Based on community feedback, the following groups emerged as those who may warrant priority for kidney offers before MOT candidates who also need a kidney:

- **Pediatric candidates:** Pediatric candidates were mentioned more than any other group for receiving priority in kidney allocation above adult MOT candidates, in large part because of the unique anatomy specifications of pediatric candidates and the ethical implications for pediatric transplantation. Some within the community are in favor of prioritizing all pediatric candidates rather than certain pediatric groups. Members of the community also voiced their concern, and frustration, regarding the use of low KDPI kidneys being used in adult MOT rather than pediatric kidney-alone or pediatric MOT. Additionally, some in the community suggested prioritizing pediatric MOT candidates over pediatric kidney-alone and most adult multi-organ and kidney-alone candidates.
- **High CPRA candidates:** Highly sensitized candidates, often defined as candidates with a CPRA of 98 percent or higher, were another frequently mentioned category of candidates for prioritization. This extremely difficult to match candidate group was mentioned as needing prioritization over MOT candidates.
- **Medically urgent kidney-alone candidates:** Medically urgent kidney-alone candidates were a frequently mentioned group that should receive priority over non-medically urgent MOT candidates.
- **Prior living donors:** Prior living donors were also mentioned as deserving of some level of priority. Commenters pointed out the selflessness of living donors should be repaid in their time of need. Several acknowledged that not providing living donors with priority could disincentivize others from becoming living donors. Prior living donors who donated within the United States currently receive some priority in kidney-alone allocation, and under new continuous distribution frameworks.
- **Kidney-Pancreas Candidates:** The Committee also received feedback regarding the classification of kidney-pancreas (KP) as a multi-organ transplant combination that must be prioritized among other multi-organ combinations. Nearly every pancreas transplant is accompanied with a simultaneous kidney transplant; both patients and professionals commented that having these candidates compete for kidneys designated for other multi-organ combinations puts pancreas candidates at a disadvantage. Accordingly, public comment recommended treating kidney-pancreas candidates more similarly to kidney candidates in terms of looking for opportunities to increase access to transplant for these candidates relative to other kidney-multi organ candidates, particularly given the high waitlist mortality risk for kidney-pancreas candidates.

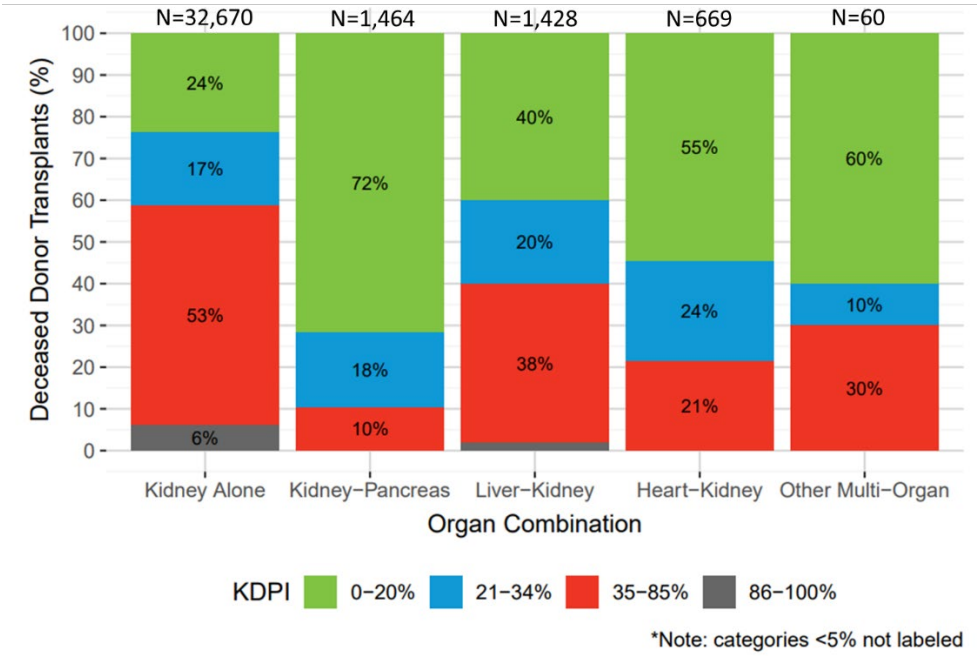
Since the January 2023 public comment period, the Committee has been exploring ways to prioritize certain kidney-alone candidates relative to certain multi-organ candidates. It is clear from public comment that there is broad community support for prioritizing pediatric candidates, candidates with a high CPRA, and medically urgent candidates above MOT candidates that do not fit into these categories. Existing kidney-pancreas and kidney allocation policies prioritize between among these groups,[4] but kidneys may not be offered as primary on the pancreas-kidney or kidney-alone match run until the OPO has worked through required kidney multi-organ offers on the heart, lung, and liver match runs.

One approach to potentially balance access to transplant between kidney multi-organ candidates and kidney-alone and kidney-pancreas candidates outlined in the 2023 concept paper is to require one kidney to go to a kidney-alone candidate if the other kidney is placed with a multi-organ candidate. This approach received some support in public comment, particularly from those interested in improving access to transplant for pediatric kidney-alone candidates. The Committee discussed limiting this approach to when both kidneys are available from donors with a KDPI between 0-34%, since those kidneys are preferred for pediatric kidney candidates and kidney-pancreas candidates as well as for kidney multi-organ candidates.[5] The Committee requested analysis on the potential impact of this approach.

The Committee reviewed deceased donor transplants by organ combination and KDPI, as shown in **Figure 1**. Between March 15, 2021, to December 31, 2022, 79% of heart-kidney transplants; 70% of "other" kidney-multi-organ transplants; 60% of liver-kidney transplants; and 90% of kidney-pancreas transplants included a kidney with a KDPI between 0-34%, compared to just 41% of kidney-alone candidates. Because KDPI is annually mapped to a reference population of deceased donors in the United States with a kidney recovered for the purpose of transplantation in the prior calendar year,[6] about 34% of donors each year would be expected to have kidneys with KDPI between 0-34%.

[4] See *Policy 11.4 Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings* and *Policy 8.4 Kidney Allocation Classifications and Rankings*.
[5] OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary for June 14, 2023, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/vsqllxvg/20230614_mot-committee-meeting-summary.pdf.
[6] "A Guide to Calculating and Interpreting the Kidney Donor Profile Index (KDPI)," OPTN, updated April 19, 2023, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/j34dm4mv/kdpi_guide.pdf.

Figure 1: Deceased Donor Transplants by Organ Combination and KDPI, 3/15/2021 – 12/31/2022[7]



The Committee also reviewed analysis on donors who donated both kidneys and recipient type, including whether the kidneys were placed with multi-organ candidates, kidney-pancreas candidates, or kidney-alone candidates, as summarized in **Table 1**. For about 82% of donors from whom both kidneys were transplanted, both kidneys went to kidney-alone recipients. For 2% of those donors (n = 353), neither kidney went to a kidney-alone recipient and both kidneys went either to a multi-organ recipient or a kidney-pancreas recipient.

Table 1: Placement of Kidneys from Donors from Whom Both Kidneys Were Transplanted, 3/15/2021 – 12/31/2022[8]

Organ Combination	Total Number of Donors	% of Donors
Both kidneys placed with multi-organ recipient	85	< 1%
Both kidneys placed with kidney-pancreas recipients	2	< 1%
1 kidney placed with multi-organ recipient, 1 kidney placed with kidney-pancreas recipient	266	2%
1 kidney placed with multi-organ recipient, 1 kidney placed with kidney-alone recipient	1,612	9%
1 kidney placed with kidney-pancreas recipient, 1 kidney placed with kidney-alone recipient	1,176	7%
Both kidneys placed with kidney-alone recipient	13,924	82%
Total	**17,065**	**100%**

A smaller proportion of these donors had kidneys with a KDPI between 0-34%, as summarized in **Table 2**. For about 70% of donors with KDPI 0-34% from whom both kidneys were transplanted, both kidneys went to kidney-alone recipients. For 4% of those donors (n = 296), neither kidney went to a kidney-alone recipient and both kidneys went either to a multi-organ recipient or a kidney-pancreas recipient.

[7] Dzhuliyana Handarova and Julia Foutz, "Examining Kidney Priority for Multi-Organ Candidates Compared to Kidney Alone Candidates," OPTN, Descriptive Data Request for the Ad Hoc Multi-Organ Transplantation Committee, May 26, 2023.
[8] Ibid.

Table 2: Placement of Kidneys from Donors from Whom Both Kidneys Were Transplanted by KDPI, 3/15/2021 – 12/31/2022[9]

Organ Combination	Total Number of Donors with KDPI 0-34%	% of Donors with KDPI 0-34%
Both kidneys placed with multi-organ recipient	61	<1%
Both kidneys placed with kidney-pancreas recipients	0	0%
1 kidney placed with multi-organ recipient, 1 kidney placed with kidney-pancreas recipient	235	3%
1 kidney placed with multi-organ recipient, 1 kidney placed with kidney-alone recipient	994	15%
1 kidney placed with kidney-pancreas recipient, 1 kidney placed with kidney-alone recipient	1,046	15%
Both kidneys placed with kidney-alone recipient	4,502	66%
Total	**6838**	**100%**

The Committee estimated that if a policy had been in effect that would have required one kidney to go to a kidney-alone candidate if the other kidney went to a multi-organ or kidney-pancreas recipient, then about 150 additional kidneys would have gone to kidney-alone candidates. Based on public comment feedback that kidney-pancreas candidates should be considered along with kidney-alone candidates in terms of priority, the Committee also considered the impact of a similar policy that would have required one kidney to go to either a kidney-alone candidate or a kidney-pancreas candidate if the other kidney went to a multi-organ recipient. In this case, the Committee estimated that only about 30 additional kidneys would have gone to kidney-alone or kidney-pancreas candidates.

Given the relatively small impact of the change relative to the proportion of kidney transplants performed each year, the Committee discussed whether the potential benefit justified the allocation change. Pediatric representatives of the Committee noted that while the overall numbers are small, it is significant relative to the proportion of active pediatric kidney candidates on the waiting list, which was 310 candidates based on OPTN data as of November 30, 2023.[10] Pediatric kidney candidates receive high priority in kidney allocation for 0-34% KDPI kidneys, just behind 100% highly sensitized and prior living donor candidates, as shown in **Table 3**.

[9] Ibid.
[10] https://optn.transplant.hrsa.gov/data/, accessed December 1, 2023.

Table 3: Priority for Pediatric Candidates in Kidney Allocation[11]

Sequence A KDPI: 0% to ≤20% (and en bloc)	Sequence B KDPI: >20% to <35%	Sequence C KDPI: ≥35% to ≤85%	Sequence D KDPI: >85%
• 100% Highly Sensitized • Inside Circle Prior Living Donor[a] • **Inside Circle Pediatrics** • Inside Circle Medically Urgent[b] • 98%-99% Highly Sensitized • 0-ABDRmm • Inside Circle Top 20% • EPTS • 0-ABDRmm (All) • Inside Circle (All) • **National Pediatrics** • National (Top 20%) • National (All)	• 100% Highly Sensitized • Inside Circle Prior Living Donor[a] • **Inside Circle Pediatrics** • Inside Circle Medically Urgent[b] • 98%-99% Highly Sensitized • 0-ABDRmm • Inside Circle Safety Net • Inside Circle (All) • National (All)	• 100% Highly Sensitized • Inside Circle Prior Living Donor[a] • Inside Circle Medically Urgent • 98%-99% Highly Sensitized • 0-ABDRmm • Inside Circle Safety Net • Inside Circle (All) • National (All) • Inside Circle (Dual) • National (Dual)	• 100% Highly Sensitized • Inside Circle Medically Urgent • 98%-99% Highly Sensitized • 0-ABDRmm • Inside Circle Safety Net • Inside Circle (All) • Inside Circle (Dual) • National (All) • National (Dual)

The Committee also noted that allowing the OPO to make primary offers on the kidney-pancreas and kidney match runs after one of the kidneys has been placed with a multi-organ recipient may reduce the extent to which multi-organ allocation impedes the allocation of other organs and thereby reduce the cold ischemic time on the remaining kidney. The Committee requests feedback on whether the OPTN should require one kidney to be offered to kidney candidates if the other kidney is placed with a multi-organ recipient for donors from whom both kidneys are available and the donor KDPI is between 0-34%. Such a policy could be implemented either for the current classification-based system of kidney allocation or for the future continuous distribution kidney allocation system since it does not impact the actual ordering of candidates on the match run. Instead, the policy would provide more direction to OPOs as to when to make primary offers on the kidney match run. The Committee also requests feedback as to whether kidney-pancreas candidates should be grouped with kidney-alone candidates or kidney multi-organ candidates for the purpose of this policy.

While the Committee considered prioritizing certain kidney-alone candidates ahead of multi-organ candidates, the Committee agreed that it is still appropriate for OPOs to offer kidneys to multi-organ candidates ahead of kidney-alone candidates due to the complex and technical nature of multi-organ procurements and transplants.[12] While there may be situations in which pediatric kidney candidates need longer vessels recovered with the kidney, the Committee agreed these instances are not common and could be addressed on a case-by-case basis and do not need special consideration in policy.

Policy Guidance for OPOs

In response to the 2023 concept paper, the community consistently requested clear guidance regarding

[11] "Addressing Medically Urgent Candidates in the New Kidney Allocation System," OPTN, accessed December 20, 2022, https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/addressing-medically-urgent-candidates-in-the-new-kidney-allocation-system/#TK_FAQ.

[12] OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary for June 14, 2023, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/vsqllxvg/20230614_mot-committee-meeting-summary.pdf.

multi-organ allocation for organ procurement organizations. Commenters stated the need for clarity around multi-organ allocation to assist in decreasing the time between allocation and transplant.

As part of the Committee's effort to address better guidance within MOT allocation the Committee will examine OPTN Policy *5.6.D Effect of Acceptance*, which is known to create confusion for OPOs during MOT allocation. As a result, the Committee has released the *Modify Effect of Acceptance Policy* proposal, currently available for public comment.[13]

The Committee has been evaluating additional solutions to provide clarity for OPOs within OPTN policy on how to proceed through multi-organ allocation. The Committee could propose delineating an order for OPOs to work through the various organ match runs, for example, requiring OPOs to make primary offers off the heart and heart-lung match runs first and then specify a point at which OPOs may then make primary offers on the lung match run, followed by the liver, intestine, kidney-pancreas, pancreas, kidney, and vascularized composite allograft (VCA) match runs. The Committee requests feedback on if and how expected waitlist mortality or graft survival should be incorporated into the prioritization of candidates across different match runs.

Since its creation in 2021, the Committee has focused on eligibility criteria as a policy solution to balance access to transplant between single and multi-organ transplant candidates.[14] However, with changes to allocation policies that have resulted in placing organs with candidates at longer distances,[15] OPOs have reported increased challenges with multi-organ allocation policies that designate candidates at relatively high sequence numbers as candidates who qualify for required multi-organ offers.[16] The feedback suggests that it would be beneficial for policy to define a point earlier on each organ-specific match run at which point OPOs may proceed with allocating other organs and are no longer bound to multi-organ required offers, and for the OPTN Computer System to mark these thresholds clearly on the organ-specific match runs. The Committee requests feedback on whether such policy and system changes would aid OPOs in following a match run order specified by policy.

Next Steps

The Committee will use this feedback to begin developing policies addressing the concerns of the community around multi-organ and kidney-alone allocation policies. The Committee will continue to explore ways to provide clarity for OPOs in allocation policy.

Future changes could also include consolidating multi-organ policies into one policy to better assist OPOs with identifying which required shares take priority over other required shares.

[13] Modify Effect of Acceptance Policy, OPTN Public Comment Proposal, January-March 2024.
[14] See the Committee's first public comment proposal, "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/npslvryi/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation_winter-2022-pc.pdf.
[15] Samantha Weiss and Chelsea Weibel, "Lung Continuous Distribution Six Month Monitoring Report," OPTN, Descriptive Data Request for the Lung Transplantation Committee, October 27, 2023, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/4feooi1h/data_report_lung_cd_6month_20231027.pdf.
[16] OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary for September 13, 2023, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/s2yhwy5d/09132023_mot-committee-meeting-summary.pdf. See also OPTN Organ Procurement Organization Meeting Summary for September 19, 2023, accessed December 1, 2023, https://optn.transplant.hrsa.gov/media/rakfrlg0/20230919_optn-opo-meeting-summary_final.pdf.

NOTA and Final Rule Analysis

The Committee submits this paper under the authority of the National Organ Transplant Act (NOTA) to "establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,"[17] and the OPTN Final Rule, which states, "the OPTN Board of Directors shall be responsible for developing... policies for the equitable allocation of cadaveric organs"[18,19] which "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[20] Feedback provided on this paper will be used to develop a policy proposal that creates new rules for organ procurement organizations on offering organs from multi-organ donors to kidney-alone and kidney multi-organ candidates, including kidney-pancreas, heart-kidney, lung-kidney, and liver-kidney candidates.

Conclusion

The Committee aims to establish an updated framework for kidney multi-organ allocation to improve equity and efficiency in multi-organ allocation. The Committee requests community feedback on how to best achieve this goal to inform a future policy proposal.

Considerations for the Community

The Committee requests feedback on all aspects of this paper, including the following questions:

MOT vs. Single Kidney Offers

- Do patients and donor family members support efforts to improve access to transplant for kidney candidates, even if it means that candidates registered for multiple organs may need to wait longer for a suitable donor?
- Should kidney-pancreas candidates be considered multi-organ candidates?
- When both kidneys are available from a donor with a KDPI between 0-34 percent:
    - Should one kidney be allocated to MOT (including KP), second kidney to kidney alone?
    - Should one kidney be allocated to MOT, second kidney to KP or kidney alone?
    - What are the potential impacts to KP and pediatric candidates?
- How should MOT candidates be prioritized when there is only one kidney available?

Policy Guidance for OPOs

- Should policy direct the order in which OPOs allocate organs? If so, how should expected waitlist mortality or graft survival be incorporated into the prioritization of candidates across different match runs?
- What additional policy or system considerations would OPOs need to follow a match run order directed by policy?
- Do patients and donor family members support efforts to promote more consistency in how organ allocation is managed by OPOs across the country?

[17] 42 USC §274(b)(2)(B).
[18] 42 CFR 121.4(a)(1).
[19] 42 CFR 121.8(a).
[20] 42 CFR 121.8(a)(4).