March 15, 2023

The Organ Procurement and Transplantation Network
c/o United Network for Organ Sharing
700 N 4th St
Richmond, VA 23219

Health Resources and Services Administration, HHS
5600 Fishers Lane
Rockville, MD 20857

To whom it may concern:

The Kidney Transplant Collaborative ("KTC") thanks the Organ Procurement and Transplantation Network ("OPTN") and the Health Resources and Services Administration ("HRSA") for the opportunity to comment on the OPTN proposal to reform its organ distribution policies and adopt the proposed Continuous Distribution of Kidneys and Pancreata Committee Update (the "Continuous Distribution" proposal).[1] We join with living donors and others in urging the OPTN to modify the Committee's Continuous Distribution proposal on reallocation of kidney distribution to maintain the current policy prioritizing allocation to living donors who later require a transplant.

As the OPTN and HRSA already know, tens of thousands of living donors over the years have been promised priority access should they require a transplant. It would be a significant breach of the OPTN's commitment to these donors to now "change the rules" on them. As important, future living donors, whether directed or undirected, will earn and deserve the right to be prioritized on the waitlist if they later have a need for a transplant. Changing the current policy will have a material negative impact on the willingness of future living donors to donate, exacerbating the lack of available organs for transplant. Thus, without commenting on the remainder of the OPTN Continuous Distribution proposal, we urge the OPTN in the strongest terms to maintain the prioritization of living donors on the waitlist.

About KTC: KTC is a national non-profit advocacy organization that is dedicated to increasing kidney transplants while decreasing the financial obstacles and other challenges kidney recipients, donors, and families often experience during the kidney transplantation process. KTC is a relatively new organization, founded in February 2021, with the sole and specific mission of supporting programs and policy solutions to increase kidney transplants and reduce transplant

[1] *See* https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-kidneys-and-pancreata-committee-update/.

barriers. KTC has engaged experts with technical, clinical, and quality expertise from the renal and transplant community to serve on the Board of Directors and Expert Advisory Panel, who assess the organization's grant and policy priorities.

In the past year, KTC has authorized approximately $3.2 million to fund five grant proposals directed towards increasing kidney transplants. The grants will address pulstile perfusion of kidneys from procurement to delivery, using machine learning to improve utilization and reduce discards, using shared decision making in the kidney transplant process, rapid organ recovery from donation after uncontrolled circulatory death, and exploring deceased kidney donor chains.[2] KTC also has developed an extensive policy proposal to increase living donation in the United States, which has been widely circulated and is under active discussion by policyholders.[3] As such, we have a particular interest and expertise in living donation policy, which leads us to urge HRSA and the OPTN to maintain and continue its prioritization of living donors who are in need of a transplant as it exists in current policy, rather than treat living donors like all others on the waitlist.

We Urge the OPTN To Modify the Continuous Distribution Proposal and Maintain the Current Policy Prioritizing Living Donors: As the OPTN and HRSA are aware, current policy, memorialized at Section 8.4 of the OPTN Policy Manual, gives priority to the small number of living donors who later in life may be in need of a transplant.[4] More specifically, living donors are given four "points" towards prioritization for transplant, which gives them near absolute priority over otherwise similarly-situated candidates and elevates them to near to the top of the list. "[5]

The current policy protects the very low number of living donors that are even in need of a later transplant (estimated at between one half of one percent to one percent of all living donors),[6] and appropriately recognizes that living donors have already contributed into the system at great personal, health, and often financial cost by undergoing the donation procedure and contributing their organ to another. This altruistic act is in and of itself worthy of prioritizing living donors in

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[2] https://kidneytransplantcollaborative.com/grants/

[3] https://kidneytransplantcollaborative.com/policy-priorities/

[4] https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf, Section 8.4. *See also* *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/the-new-kidney-allocation-system-kas-frequently-asked-questions/#bookmark10*

[5] https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/?utm_source=NKDO&utm_campaign=06739e744d-EMAIL_CAMPAIGN_2022_08_15_06_42_COPY_01&utm_medium=email&utm_term=0_db69322dec-06739e744d-1392479265. Only the very difficult to match receive a higher priority under current policy.

[6] Wainwright, et al., Delays in Prior Living Kidney Donors Receiving Priority on the Transplant Waiting List; Clin J Am Soc Nephrol. 2016 Nov 7; 11(11): 2047–2052; doi: 10.2215/CJN.01360216 *See also* https://khn.org/news/what-happens-when-a-living-kidney-donor-needs-a-transplant/

the rare instances where they later are in need of a transplant, and is particularly fitting given that through their donation living donors have previously reduced the waitlist for others.
In contrast to the existing living donor policy which provides previous donors with near absolute priority, the proposed policy would assign living donors a yet-to-be-determined number of "points" that, with points for other attributes, would determine their prioritization for future kidneys. As explained by the OPTN: "[i]n the new continuous distribution framework, each attribute will have a specific weight, meaning some attributes will have more effect than others on the total score, yet no one attribute will decide an organ match. A candidate's total score will determine their prioritization on the match run."[7] We believe that the new framework effectively compromises the prioritization process for living donors, who despite a 5% credit on their composite allocation score for their previous donation,[8] will not receive the priority currently promised to them. Further, if the Continuous Distribution process is adopted, future living donors will surely think twice before agreeing to donate – defeating the very purpose of the policy.

The proposed Continuous Distribution policy disrespects the sacrifice made by previous living donors and is a disincentive to potential donors who are a critical source of kidneys for transplant today. Every measure should be taken to ensure that living donors are afforded priority access to transplant in the highly unlikely event that a living donor later requires a transplant organ. This is not only critical to keep the promise that the OPTN has made to the over 100,000 living donors who have already contributed to the system and assisted in reducing waiting times, but is also necessary to ensure that both directed and non-directed living donors are not discouraged but rather, encouraged to continue to participate in the system. For these reasons, we urge the OPTN and HRSA to revise the proposal and ensure that living donors are prioritized on the wait list.

Response to Others' Comments: As noted above, we join in the comments of the dozens of living donors who have already urged the OPTN to maintain its current priority policy for living donors. We also appreciate the comments of the OPTN Ethics Panel that: "the Kidney and Pancreas Committees keep in mind the altruism and self-sacrifice of the living donor as perhaps a separate factor than the other continuous distribution attributes to ensure living donors receive priority." The Ethics Panel's observation that: "the Committees should keep in mind the impact of the perception of "changing the rules" for those who have already made a living donation on public trust in the system" is also particularly important.

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[7] HRSA Policy, note 3.
[8] The OPTN has not published the ranking scale for kidney donors, but for lung donors the OPTN has noted it will assign the following credits for the different factors under consideration: waitlist survival 25%, post-transplant outcomes 25%, biological disadvantages 15%, blood type 5%, CPRA 5%, height 5%, patient access 25%, pediatric 20%, prior living donor 5%, placement efficiency 10%, travel efficiency 5% and proximity efficiency 5%. In effect, prior living donation is not accounted for in the same way as travel or proximity.

That said, we strongly disagree with and question the scientific basis of the Ethics Panel's observation that "expanded priority for prior living donors may increase racial and socioeconomic disparities. Therefore, the prior living donor attribute should be modeled and carefully balanced by the Committees." Reducing living donor prioritization is not the answer to the disparities problem – fixing the disparities problem is the solution to the disparities problem and KTC joins in the effort to do so. Reducing prioritization for living donors to "fix" the disparities problem will only result in fewer living donors. The number one unmet need in transplant today is the lack of available kidneys.

Conclusion: We urge the OPTN and UNOS to keep its promise to prior living donors and to maintain that promise for future living donors – living donors should be given the highest prioritization on the wait list. Thus, we call on the OPTN to modify the Continuous Distribution proposal and to clarify that current and future living donors will maintain the prioritization they hold in current policy.

We welcome any questions or comments you have, and would welcome the opportunity to speak with you further on this issue. Please do not hesitate to contact KTC's policy counsel, David Farber, at dfarber@kslaw.com or at 202.626.2941. We appreciate your consideration of these comments and look forward to further dialogue with the OPTN and HRSA on these important issues.

Respectfully submitted,

/s/ *Louis Diamond*

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