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Notice Number: HSB115C1031
Title: Request for Information on the Organ Procurement and Transplantation
Network (OPTN)
Date of Issuance: April 8, 2022
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May 9, 2022

Via Electronic Submission to NNazawa@hrsa.gov

Health Resources and Services Administration
Department of Health and Human Services
Office of Acquisition Management & Policy
5600 Fishers Lane
Rockville, MD 20852

RE: Request for Information by the Health Resources and Services Administration regarding the Organ Procurement and Transplantation Network (OPTN) – Notice # HSB115C1031

To Whom it May Concern:

The Kidney Transplant Collaborative (“KTC”) thanks the Health Resources and Services Administration (“HRSA”) for the opportunity to respond to its Request for Information (“RFI”) seeking to strengthen and improve components of the Organ Procurement and Transplantation Network (“OPTN”) contracting process.¹ We specifically offer comments on how HRSA can increase organ donation with a focus on improving kidney donation by incorporating several of the recommendations made by the National Academy of Sciences, Engineering and Medicine (“NASEM”) in its recent February 2022 report on transplantation. We hope our comments will aid the Office of Acquisition in both improving OPTN operations and in improving patient outcomes and significantly increase donor organs utilization for transplantation, thereby also increasing transplantation equity and accessibility.

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 barriers. KTC has engaged experts with technical, clinical, and quality expertise from the renal

¹ See Press Release, Health Resources and Services Administration, HHS Releases Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network (April 8, 2022) <https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi>.



and transplant community to serve on the Board of Directors and Expert Advisory Panel (EAP), who assess the organization's grant and policy priorities.

In the past four months, 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. Notably, following the kickoff of its grant program in mid-2021, KTC received nearly four times the anticipated number of grant proposals from nationally recognized institutions across the country, with 70 different proposal seeking over \$43 million in funding. Several common themes and issues emerged from the proposals, including improving living donor compensation, expansion of paired and chain kidney donation programs, patient engagement regarding organ acceptance and discard rates, and transplant waitlist management. Projects proposed various strategies to address these issues, including educational, medical and technological interventions, engaging in strategic partnerships and implementing creative models to address staffing, processes and organizational infrastructure.

We highlight our recent experience because the grant proposal response, as well as the information contained in the proposals, underscores that significant gaps continue to be prevalent in the kidney transplant system today which the upcoming HRSA contract could address.

RESPONSE TO QUESTIONS:

HRSA Question F: "Organ Usage -- The NASEM report identifies concerns with the current high level of organ non-usage (discards), estimated at an unacceptable 25%. Over the past several years, the OPTN Collaborative Improvement and Innovation Network (COIIN) projects and the current CMS/HRSA End Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) have worked to build and share best practices models to aid the community in addressing variables that adversely impact organ usage. HRSA is seeking feedback related to the following questions on increasing organ usage and simultaneously decreasing organ non-usage (discards).

1. Describe how you would/a vendor could support the OPO performance improvement activities to decrease discarded organs and further increase the use of organs.
2. How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?
3. Describe the steps you would/vendors could take to improve transparency around the organ matching and acceptance process for transplant candidates, transplant recipients, other affected patients, organ donors and family members served by the OPTN."

KTC Response: KTC applauds HRSA's request for this information and urges the upcoming procurement to address the issues identified in the NASEM Report. As identified in the report, organ discard rates are unacceptably high, and many discarded organs represent a lost transplant



opportunity to an individual on the waiting list. For this reason, we urge HRSA to incorporate the following recommendations of the NASEM Report, including those addressing organ discard rates:

- Improving equity (Recommendation 3);
- OPTN accelerate continuous distribution framework (Recommendation 4) and eliminate pre-dialysis waiting time (Recommendation 5);
- OPTN resolve discrepancies in organ allocation algorithms, (Recommendation 7), including the calculation of eGFR;
- Increased transparency around organ offers/declines and engagement and partnership with patients; (Recommendation 10);
- Align reimbursement with decided behavior and outcome (Recommendation 14);
- make it easier for transplant centers and surgeons to say yes to organ offers and ensure transplants can occur seven days per week (accounting for the “weekend effect”) (Recommendation 9);
- Development of national quality goals (Recommendation 1), including development of a national quality dashboard and partnership with the National Quality Foundation;
- Require donor care units for each OPO (Recommendation 11);
- Embed Quality Improvement across the transplantation system (Recommendation 13);
- Improve OPTN policy making process (Recommendation 2); and
- Create a state-of-the-art data system (Recommendation 8).

We appreciate that many of these recommendations touch on other questions posed in the RFI, but urge HRSA to take a broad and expansive view of the recommendations identified above as we believe they will fundamentally alter and improve the transplant process for all stakeholders. For example, improving health equity within the transplant program will result in less discarded organs, as well as deliver numerous other tangible benefits to the transplant program. Similarly, requiring that the OPTN implement practices across the country to ensure that transplant centers “say yes” to available organs, and also address the delays in scheduling procedures due to the “weekend effect” will significantly improve transplant programs across the country.

The NASEM report includes numerous comprehensive recommendations on each of the subject areas noted above, as well as those addressed in several of the other questions posed in the RFI. We encourage HRSA to incorporate the NASEM proposals identified in the above response in its upcoming OPTN bid documents.



We again thank HRSA for its thoughtful and wide-ranging RFI and hope the above comments will assist the Agency in further formulating new policies to address and improve kidney transplantation in the United States through the upcoming OPTN contract process. As the Agency itself points out, the current waiting list is too long and growing, and more needs to be done to increase kidney transplants across our country. We welcome further partnership with HRSA on these important issues. To that end, we thank you for consideration of these comments and welcome any questions or follow up that you may have.

Please feel free to contact me at 301.832.2734 or ldiamond@kidneytransplantcollaborative.com if we can provide any additional information.

Sincerely,

Louis H. Diamond

Dr. Louis Diamond
President & CEO
Kidney Transplant Collaborative (KTC)