Health Resources and Services Administration [HRSA] Request for Information

HHS/HRSA/OAMP
5600 Fishers Lane
Rockville, Maryland 20857-5600
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611
Incumbent: United Network for Organ Sharing (UNOS)
Date of Issuance: April 8, 2022
Point of Contact: NInazawa@hrsa.gov

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NATIONAL KIDNEY FOUNDATION®

May 23, 2022

The Honorable Carole Johnson
Administrator
Health Resources and Health Administration (HRSA)
5600 Fishers Lane
Rockville, Maryland 20857-5600

Dear Administrator Johnson,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the Health Resources and Services Administration (HRSA) Request for Information (RFI) regarding the Organ Procurement and Transplant Network (OPTN).

We respectfully submit our comments on behalf of the 37 million individuals, 1 in 7 adults, in the United States estimated to have chronic kidney disease (CKD).[1] The prevalence of kidney failure is expected to increase dramatically, possibly exceeding one million people who may need access to the transplant waitlist by 2030.[2] There are not enough deceased or living donor organs to meet current or future needs creating a public health emergency in need of immediate attention. Although 24,669 people received a kidney transplant in 2021, far too many are still waiting, never access the transplant waitlist, or never learn that a transplant is an option.

NKF appreciates HRSA's efforts to improve the organ and transplant system and optimize the OPTN contract to ensure that each component maximizes organ donation and transplantation. We champion the primary objectives outlined in the RFI for the improvement of the OPTN contract:

1. Increase accountability in OPTN operations, including board governance, financial structures, data quality transparency, and policy development;
2. Enhance the usability and performance of the OPTN IT system and related tools; and
3. Strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process.

Our comments follow the suggested format requested in the RFI.

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[1] Centers for Disease Control and Prevention. *Chronic Kidney Disease in the United States, 2021*. Centers for Disease Control and Prevention; 2021.

[2] McCullough KP, Morgenstern H, Saran R, Herman WH, Robinson BM. Projecting ESRD Incidence and Prevalence in the United States through 2030. J Am Soc Nephrol. 2019 Jan;30(1):127-135. doi: 10.1681/ASN.2018050531. Epub 2018 Dec 17. PMID: 30559143; PMCID: PMC6317596.

Comments:

A. OPTN Technology—IT System

1a. We believe that HRSA should create two separate contracts for the Information Technology (IT) Infrastructure and one for other OPTN priorities. The current IT architecture is outdated and fraught with inefficiencies that impair organ donation and transplantation. The OPTN contractor should not own any technology associated with the organ donation process, including donor management and allocating organs for transplant. Separating the two contracts allows OPTN to leverage significant improvements in information technology and mitigate the risk of disruption to the donation and transplant process. Consultation with IT experts is germane to enhance data collection, organ allocation, transplantation, and usability.

1b. We strongly support the need for data transparency and implementation of information technology that facilitates these changes, such as application programming interfaces. The current OPTN contractor has not kept pace with the rapid changes in healthcare IT standards, including implementing fast healthcare information resources (FHIR) across EMRs, standard data models, or a robust and transparent data dictionary for the data captured from transplant centers or OPOs.

1d. We believe that it is critical to establish meaningful collaborations with EMR providers, clinical informaticians, and transplant experts to identify performance improvement areas for data collecting and reporting and reduce inequities within the transplant ecosystem.

3. We believe that data transparency of organ donor hospitals, OPOs, and transplant centers must be priotitized in order to improve organ allocation processes. The lack of data transparency creates significant barriers to care and inequities for the entire population that could benefit from transplantation. Data collected from OPOs and transplant centers are out of date, unaudited, incomplete, and self-reported, making it impossible to develop modern quality measures, specifically for steps in the pre-transplant process. Patients need real-time data, or as close to real-time as possible, to make informed decisions about transplantation. The current delay in data does not accurately portray the current state of organ donation and transplantation.

The transplant waitlist is poorly maintained because of inconsistent communication between transplant centers, dialysis facilities, and patients or caregivers due to the current antiquated IT architecture. Patients on the waitlist are frequently unaware of their waitlist status—active or inactive-- and receive little or no information from the transplant centers. This absence of communication among patients, their dialysis facilities, and transplant centers represents a failure of the OPTN to improve communication between various stakeholders in transplantation, resulting in inefficiencies of allocation and the perpetuation of silos of care. Patients face life-threatening consequences because the IT infrastructure stymies efficient allocation. For example, nearly one in five kidneys is offered to a deceased person still on the waitlist because the transplant center is unaware that the patient has died, and deceased candidates receive a median of 4 organ offers before being removed from the waitlist.[3]

HRSA should also require the OPTN contractor to inform patients of the criteria used by transplant centers for accepting offered organs. Transplant centers do not share these criteria with patients. Educating patients on this information would empower patients to choose which center would suit them best. Bypass filters are used by transplant centers to automatically screen-out offered kidneys from donors with specific clinical characteristics. For example, donor age criteria can be set such that centers do not receive national organ offers from donors above a pre-specified age. While these filters were initially designed to help accelerate allocation, their use needs to be monitored and researched by CMS to determine the impact.[4] These bypass criteria often can result in dramatic changes in the probability of transplantation because it shrinks the pool of donor organs to which patients at a given transplant center have access.

Prioritize quality assurance efforts and utilize an IT platform that fosters improved data collection for better patient outcomes. Practices such as out-of-sequence placements, list diving, and the decline of many organ offers also contribute to inefficiency and exacerbate inequities in the transplant system. HRSA must ensure that prospective contractors construct algorithms to combat these practices and provide a more efficient and equitable system in future contracts.

Finally, we were deeply troubled by OPTN’s recent announcement about the addition of 35,000 verified deaths to the standard analytical files. This adjustment illustrates the failure of the current system to capture data from a range of sources and cross-reference it to ensure maximum efficiency. Further, OPTN’s announcement lacked urgency or even recognition of the gravity of data inconsistencies and their implications for transplantation-related research. This incident reinforces the critical need for transparency and the need to separate the IT contract from other OPTN requirements to ensure that patients and the system benefit from the cutting-edge technologies that can eliminate these inconsistencies and inefficiencies. HRSA must also determine how death data is collected and verified with the OPTN contractor and CMS to mitigate an error of this magnitude in the future.

B. Data Collection Activities

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[3] Husain SA, Winterhalter FS, Mohan S. Kidney transplant offers to deceased candidates. Am J Transplant. 2018 Nov;18(11):2836-2837.

[4] King KL, Husain SA, Mohan S. Trends in Transplantation Center Use of Kidneys From Deceased Donors With Positive Hepatitis C Virus Nucleic Acid Testing. Am J Kidney Dis. 2020 Nov;76(5):743-746.

1. We support HRSA's goal to develop performance metrics and standards for organ donation, allocation, recovery, and transplant. We applaud HRSA in its desire to engage with patients and donor families to learn about the measures they value and firmly advocate for the inclusion of patient and donor family voices in each data development phase. It cannot be stressed enough: data transparency needs to be enforced among donor hospitals, organ procurement organizations, and transplant centers. Without honest data-sharing compliance from the stakeholders within the transplant ecosystem, the process remains fractured, and patients suffer. An innovative information technology infrastructure would facilitate seamless data collection, sharing, and reporting across different platforms used by donor hospitals, OPOs, and transplant centers.

Patients treasure the opportunity to receive a transplant and often inquire about the efficiency and effectiveness of the process itself. Unfortunately, current data collection from transplant centers is insufficient to address patients' concerns. We encourage the OPTN contractor to collect information that is most relevant to patients, including the following data points:

- Percentage of referrals who receive an evaluation after referral
- Time from evaluation to listing
- 1-year health-related quality of life post-transplant
- Long-term graft survival

Improved data collection is a critical component of meaningful measurement. Lastly, performance standards should align with financial incentives across all stakeholders overseeing and regulating the transplant system to encourage more patients to transplant.

2a. Current data capture systems are antiquated and need to be updated. These data systems do not currently facilitate data validation, quality checks, meaningful feedback, or avoid duplication. There is also a need for a robust and well-maintained data dictionary.

Additionally, require the OPTN contractor to establish and monitor process and outcome measures. The current inability of the MPSC to be able to generate meaningful reports on the number of out-of-sequence exceptions and other violations/exceptions is a concerning example of the limitations of the current vendor's oversight capabilities.

2d. Data reports, summaries, and infographics need to be formatted to be consumer-friendly. Data reporting should be patient-centered and simple, omitting medical or statistical jargon so that patients can easily make informed decisions about a transplant as the next possible phase in their care. Patients should not have to decipher the same data as clinicians and statisticians to decide if a transplant is the best treatment.

2e. The OPTN contractor should collect data on social determinants of health and data on patients denied an opportunity to be waitlisted, along with the reason, to better understand and determine the need. The contractor can collect this data by using links to other public and proprietary datasets to monitor the OPTN. These data linkages need to be robust, recurrent and used to develop policies that would support equity in the allocation system and the development of interventions necessary to improve access to transplantation.

C. OPTN Finances

1b. Access to data is critical to maximizing every organ donation and transplant opportunity. Currently, the OPTN contractor charges a fee for specific data reports and visualizations needed by transplant centers and OPOs to understand the impact of the allocation system on organ offers, organ acceptance, and bypass filters. Requiring payment to access process data measures is a significant hindrance to transplantation and should be prohibited.

1c. The OPTN data portal is challenging because it is difficult to understand and identify actionable information, and as previously noted, the OPTN contractor assesses a fee to access this data. We would urge the contractor to create data reports that are easy to decipher and at no cost to clinical stakeholders who need to access this information to optimize patient care.

1d. The introduction of quality measures that encourage transplant referral and waitlisting at the dialysis facility level will likely increase the number of patients referred to transplant centers. An unintended consequence is a potential change in transplant waitlisting behavior and a drastic increase in the number of individuals listed as inactive. The conflict that arises with this process is thousands of patients become waitlisted without the hope of being evaluated promptly, all while OPTN continues to receive waitlist fees. NKF would urge HRSA to monitor this situation closely and intervene quickly to address and resolve this practice if it occurs.

2. Any entity that holds the OPTN contract must create, maintain and produce a detailed accounting record of all funds received and their use. Develop public confidence by transparently sharing all money received and its use to operate with accountability.

D. OPTN Governance

1. NKF recommends decoupling the OPTN board from the UNOS board. These two entities should be separate and members of one board should be prohibited from serving on another. We also recommend that OPTN increase racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing policies and making these voices heard. HRSA should survey the OPTN board and committee members on their experience serving OPTN to assess performance and identify opportunities to ensure that the boards are representative, effective, and high functioning.

Member selection for the OPTN board, the board of the OPTN contractor, and committees should be transparent and ensure that prospective members have the requisite expertise and continuous participation engagement. Consider including external voices on the board and various OPTN committees. Public health experts with experience in bioinformatics and epidemiology, patient safety specialists, and other healthcare professional thought leaders may offer innovative solutions and changes to improve the organ procurement and transplant system.

2. We believe that a commitment to transparency dictates that all board and committee members must disclose any paid conflict of interest, such as physicians paid as medical directors for their local OPO and examples of the like. Further, the contractor must have a process to ensure that members are not involved in conflicting relationships. Members must recuse themselves when voting on issues with a conflict of interest.

3. The current OPTN regions would be equitable either in terms of patients served, population served, or volume of transplants and should no longer be used to estimate representation.

4. We reiterate our request that the contract requires the vendor to share its process for determining how volunteers are selected and assigned. The current governance of the OPTN contractor is opaque, with little clarity around the member selection process. There has been considerable turnover among UNOS staff, resulting in limited institutional memory and transparency and little desire to change the status quo. Most committees have limited relevant expertise to address the questions, often unaware of pressing issues. We strongly advise that members be vetted to assure they have the necessary knowledge and experience to serve on key committees and boards. Lastly, seek external expertise when it is not available in the committee.

E. Increasing Organ Donation and Improving Procurement

1a. Organ Procurement Organizations are the only stakeholders responsible for recovering deceased organs in the transplant ecosystem. The OPTN contractor should enforce strict oversight and accountability of OPOs to ensure every opportunity for organ donation is optimized. NKF recommends the following strategies to improve OPO performance:

Immediate data transparency—OPOs collect organ donation data that is inaccessible to the public. As an entity whose sole purpose is to serve the public, it is a disservice to patients in need of transplantation, organ donors, and donor families who make the selfless decision to donate their loved one's organs. The following metrics (at a minimum), currently captured by all OPOs, should be made readily available:

- Number of organ referrals
- Number of brain dead donors
- Number of DCD donors
- Missed organ referrals
- Conversion rate
- Approach rate

- Consent rate
- Percentage of first-person consent

Regulatory consequences for OPOs failing to respond timely to donor hospitals to evaluate potential organ donors – When donor hospitals make a referral for a patient who is not automatically clinically ruled out as an organ donor, the OPTN contractor should require OPOs to make every effort to elicit a timely onsite response for an evaluation.

Regulatory consequences for missed organ referrals – Donor hospitals should face repercussions for substandard missed referral rates. When a hospital fails to notify an OPO of a potential organ donor, critically ill patients continue to wait for a life-saving organ transplant. Further, families lose the opportunity to continue the legacy of their loved ones through the selfless gift of organ donation, and the wishes of the person who has designated their desire to donate their organs are unfairly forfeited.

Donor hospital EHR clinical trigger – Timely communication between the donor hospital and the OPO is crucial to the organ donation process. The OPTN contractor should ensure that donor hospitals deploy tools that maximize donation and facilitate prompt referral to the OPO, such as electronic clinical triggers in the EHR that prompt clinical staff to call the OPO when a provider documents specific patient criteria. For example, if a nurse charts that a patient is intubated and documents a loss of two cranial nerve reflexes or has a Glasgow Coma Scale of 5 or less, a prompt should appear notifying the nurse to call the OPO. The responsibility to refer the patient to the OPO lies with the hospital staff.

Staffing to reflect the DSA community—The OPTN contractor must call for OPOs to recruit, hire, and train staff representing the diverse racial, ethnic, and cultural communities they serve. Diversity, equity, and inclusion should be reflected across all departments within the OPO, including executive leadership, OPO professional staff, the clinical teams that interface with donor hospitals, and the teams that work with potential donor families.

2. We believe that the OPTN contractor should mandate OPO compliance with research efforts to examine and analyze practices that could improve donation, recovery, and allocation of organs. With the continuous growth of the transplant waitlist, research initiatives should include increasing the utilization of organs, decreasing organ discards, data transparency, and health equity. Please note the following suggestions for research to enhance the donation and transplant process:

Transportation: Organ transportation delays and inefficiencies have life-threatening consequences for patients on the waitlist. It is unacceptable that donated organs are discarded due to transportation inefficiencies after donors and donor families have made the selfless decision to donate organs. NKF implores HRSA, in collaboration with the OPTN contractor, to examine challenges in the transportation system and identify policies, best practices, and strategies to mitigate cold ischemia time that results in organ discards.[5]

Equity: Reducing disparities and ensuring that each donor and their family are respectfully considered and supported during the donation process.[6]

Consent training: Strengthen the skills of OPO staff responsible for approaching families for organ donation, emphasizing donor family communication best practices, implicit bias, racial equity, and trauma-informed care.

Donor management: Assess and improve clinical knowledge to maximize organ recruitment and transplantation, including perfusing organs and donation outcomes after cardiac death (DCD) and brain dead (BD) donors and organs.

Data reporting: Optimize data collection and reporting for quality assurance and performance improvement to be shared transparently with the public.

4. Education and outreach are critical components of overcoming every challenge in kidney care, including racial and ethnic bias in organ donation. The OPTN contractor could implement a multipronged organ donation and transplantation education initiative, because it has a vital role in incentivizing OPOs to build trust and awareness in historically underserved populations and communities (including racially and ethnically diverse communities).

First, OPO staff must receive consistent education on cultural sensitivity, empathy, and consent training. Obtaining consent for donation is vital to increasing the number of organs available for transplantation. OPOs have a crucial role in educating the public on organ donation and reaching out to underserved populations to address concerns or misconceptions regarding organ donation. *NKF strongly opposes race-based adjustments to the OPO metrics, which perpetuate these inequities rather than encourage OPOs to improve their service to underserved communities.

Second, OPOs must engage in community outreach and build partnerships with stakeholders and religious leaders or hospital clergy to provide family support and spiritual guidance to potential donor families. Investing in relationships within the community and providing education on organ donation and transplantation could increase authorization rates and health literacy initiatives that educate underserved, rural, and diverse communities on organ donation, living donation, and transplantation.

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[5] Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clin Transplant*. 2019;33(1):e13419. doi:10.1111/ctr.13419

[6] Guadagnoli, E., McNamara, P., Evanisko, M. J., Beasley, C., Callender, C. O., & Poretsky, A. (1999). The influence of race on approaching families for organ donation and their decision to donate. *American journal of public health*, *89*(2), 244–247. https://doi.org/10.2105/ajph.89.2.244

Third, the OPTN contractor should consider how regulatory policies can encourage OPOs to adopt best practices to overcome the effect of bias and prejudice on the ability of families to donate their loved one's organs. Examples include hiring staff representing the communities they serve and implementing frequent training on cultural sensitivity, diversity, and inclusion to improve conversations with non-White populations about donation. Prejudice and implicit bias are common elements of OPO practice. Beliefs that people of color will not donate perpetuate patterns where hospitals are less likely to refer prospective donors to the OPO. In studies, Black/African American families have declined organ donation because of insufficient time to process and discuss important issues and a lack of sensitivity and empathy during the approach process.[7] Research has also found that OPOs are more likely to approach White families over Black/African American families. [8]

Fourth, require transparent data sharing to understand how race, ethnicity, and disability impact the success of organ procurement and transplant. Transparent, verifiable, and publicly available process data, including approach, consent/authorization, and conversion rates, broken down into specific demographics (ethnicity, religion, age, location, etc.), are necessary to address and resolve disparities.

Lastly, decertify OPOs that consistently underperform, primarily due to a lack of engagement with communities of color. Donor families find organ donation to help with grief, knowing the legacy of their loved ones lives on through the selfless act of organ donation. Yet, this is often not afforded to Black families because OPOs approach them at lower rates than white families. Better data collection and reporting will reveal these inequities and incentivize performance improvement by OPOs.

F. Organ Use

1. NKF recommends a series of activities that will improve efficiency and minimize the number of organ discards:

Place urgent attention on the role of organ transportation in organ discards. Changes in the allocation system have resulted in more organs flying across the nation than ever. Dependence on commercial flights presents several challenges for transplantation that contribute to avoidable discards. Organ recovery usually occurs in the late hours when donor hospital operating rooms are less busy and when there are fewer commercial flights. Every hour a recovered organ waits to be transplanted, cold ischemia time (CIT) increases, decreasing the likelihood of transplantation. Federal regulations no longer allow organs to fly

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[7] Siminoff, L.A., Alolod, G.P., Gardiner, H.M. et al. A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation. J. Racial and Ethnic Health Disparities 8, 485–493 (2021). https://doi.org/10.1007/s40615-020-00806-7

[8] Siminoff, Laura A. PhD; Lawrence, Renee H. PhD; Arnold, Robert M. MD Comparison of black and white families' experiences and perceptions regarding organ donation requests, Critical Care Medicine: January 2003 - Volume 31 - Issue 1 - p 146-151

in the cockpit with the pilot, only as cargo, which exacerbates CIT. Kidneys with too much CIT are discarded and represent a potential life lost on the waitlist. Deceased kidneys are a scarce resource; inefficiencies in air travel should never be a reason for organ discard.

Improve the protracted process by which the current OPTN contractor commits resources to introduce changes in the IT systems. For example, the process of implementing new organ decline codes took nearly five years. This extensive delay caused by the lack of adequate IT resources highlights a problem that stems from the need to invest in modern IT infrastructure and the absence of a desire to invest proactively in the system. A state-of-the-art IT infrastructure is imperative to implement changes quickly to optimize an efficient organ allocation system.

Increase living donation and deceased donation to contribute to closing the gap between the supply of kidneys and the demand for them. NKF supports both the *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs* and *Removing Financial Disincentives to Living Organ Donation* final rule as significant steps in increasing the organ supply. We encourage iterations on the OPO final rule through sub-regulatory guidance and further regulatory action to incentivize consistently high-quality organ procurement practices.

HRSA must also maximize its authority under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation Program, administered by the National Living Donor Assistance Center (NLDAC), to raise the income eligibility threshold for assistance to, at minimum, 500% of HHS Federal Poverty Guidelines.

Prioritize efforts on improving kidney paired donation (KPD) to address the organ shortage and maximize the benefit of each living donor organ. Relatively little has been done to facilitate KPD. At a minimum, further investment in evolution and policymaking around the UNOS Kidney Paired Donation Pilot Project is warranted.

2. The OPTN contractor should consider the extent to which regulation, quality, and payment policies, and quality improvement initiatives can incentivize OPO and transplant center practices that could reduce discards as recommended by NKF's 2019 Discard Consensus Conference:[9]

- Begin the organ allocation process earlier in the donor evaluation phase.
- Improve communication between OPO and transplant surgeons--The Kidney Allocation System relies on an electronic communication platform, DonorNet, that limits verbal communication between the OPO and transplant center. The exclusive use of DonorNet without collaborative conversations between the OPO and transplant center contributes to decreased organ utilization.

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[9] Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clin Transplant*. 2019;33(1):e13419. doi:10.1111/ctr.13419

- Accelerate virtual crossmatching and send early prospective crossmatch samples.
- Require more frequent QAPI meetings with OPOs and transplant centers to review and analyze data and investigate root causes for low organ transplant rates.
- Secure "local backups" to mitigate the possibility of a kidney discard.
- Increased patient-centricity around organ offers may also contribute to reduced kidney discards.
- The OPTN contractor should consider creating an algorithm that recommends which patient group receives specific organ offers (ex., determine which patient group would benefit most from a particular organ offer to mitigate "list diving" and reduce organ discards)

Patients have an essential role in improving risk aversion and reducing discards by making their wishes clear to their care teams. Patients are often less risk-averse than their surgeons and centers. As they spend more time on the waitlist, they may accept an imperfect organ that still confers clinical value compared to dialysis. Transplant centers, nephrologists, and dialysis facilities must regularly consult patients to assess and refine their transplant goals. Increasing utilization is closely linked to reimbursement, transparency, and improved organ acceptance practices. However, it begins with a patient-centered approach to understanding the waitlisted patient's goals and preferences. Transplant programs should also promote shared decision-making with inactive waitlist patients.

3. NKF is troubled by the lack of transparency given to patients regarding organ offers declined on their behalf. Patients deserve to be active participants in their healthcare, with decision-making authority. While transplant centers are not the sole provider of direct patient care for waitlisted patients, they are responsible for communicating with patients, ensuring readiness for transplant, and educating patients about organ donation. Remaining active on the list and knowing activation status and their time on the waitlist is paramount for patients. We urge you to develop a measure that captures the percentage of waitlisted inactive patients and why they have become inactive. The following metrics are also performance standards that we would like OPTN to create to improve patient-centricity and equity in the transplant process:

- Percent of referred patients who completed the transplant evaluation
- Average time from referral to evaluation
- Average time from evaluation to listing
- Percent of patients placed on the transplant waitlist
- Breakdown of demographics and socioeconomic status of these data

The pre-transplant process is unclear; patients and providers currently have no insight into where patients are in the transplant process because communication from the transplant center to the referring provider is often slim or nonexistent. There is frequently no information on what is pending, the barriers patients face to complete an evaluation, or why patients are accepted/denied waitlisting or inactivated/activated at any time point. We would urge HRSA to investigate this concern as it impedes patient-centricity and creates hurdles to transplant access.

G. OPTN Operations and Policy Development Improvements

1. We believe that it is imperative to increase diversity, equity, and inclusion in OPTN operations and governance. It is short-sighted of the OPTN to continue to hear from the same voices. Marginalized and underrepresented groups are left out of policymaking and decisions that impact their lives and well-being. In the same way that we recommend OPOs diversify their staff to reflect their communities, we implore the OPTN contractor to do the same for their board and committees. We also encourage the contractor to collaborate with the National Quality Forum (NQF) and the National Academy of Public Administration for their federal program leadership expertise and stakeholder collaboration.

H. Stakeholder Engagement

1. We ask HRSA to consider the following feedback from our patient advocates regarding their transplant experience that can affect awareness of organ offers/acceptance:

Improve communication – "Ensure that transplant centers have adequate resources and staff to support their patients with consistent and effective communication. Patients deserve to know when they are listed for transplant and the actions they can take to maintain optimal health on the waitlist. Centers must alert patients of their waitlist status when they become listed and made inactive or delisted. Physicians, Advanced Practice Providers, Nurses, Transplant Coordinators, Social Workers, and other transplant center staff that interface with patients should adequately and compassionately share the reasons for an inactive status with patients and why they have been delisted."

Include the Patient as Part of the Care Team – "Clear and timely communication between the transplant team and patients can promote shared decision-making should be afforded to each patient. Transplant centers have complained about patient compliance; if transplant centers want improved cooperation from patients, they should prioritize shared decision-making.

Promote Cultural Sensitivity – "Clinical and non-clinical transplant center staff must practice cultural sensitivity and inclusivity to decrease patients' risk of falling through the cracks due to language barriers and cultural misunderstandings. Transplant centers need appropriate communication strategies and mechanisms to relay messages with non-English speaking patients to prevent patient isolation and poor outcomes."

Address Patients' Mental and Emotional Well-being – "Organ failure is scary. Dialysis creates added stress and anxiety. Dialysis patients face a variety of challenges—healthcare complications, lethargy (too tired to participate in common daily activities), lack of social support, and depression, to name a few. There is a general fear that patients experience when faced with organ failure and the prospect of their mortality. Organ donation and transplant surgery are overwhelming to think about. Transplant centers could assuage these feelings by communicating with their patients in as close to real-time as possible about what to expect during the process (not just once, but reminders throughout would be helpful)."

2. The NASEM report recommends each stakeholder in the organ donation and transplant system be accountable for every patent in need of transplantation, including those on the waitlist and those who are not. NKF strongly agrees. Justice, fairness, equity, and transparency are values that our organ donation and transplant system need and patients deserve. The NASEM report highlights trustworthiness, which OPOs, the Organ Procurement and Transplant Network (OPTN), and federal agencies must uphold to influence public confidence in our organ donation and transplant system. Regardless of demographic characteristics or socioeconomic status, every person should have the right to access the national transplant waitlist. Organ failure patients desperately need an equitable transplant ecosystem.

3. We would reiterate the need to amplify patient-centricity. Prioritize providing adequate education to patients that allow informed decision-making about their health care, including creating and implementing aids and tools to facilitate increased organ donation and transplant understanding and patient-provider collaboration.

The National Kidney Foundation (NKF) would like to thank the Health Resources and Service Administration again for the opportunity to comment on the Request for Information regarding the Organ Procurement and Transplant Network. We welcome any questions about our recommendations and collaboration to improve the American organ donation and transplant system. Please contact Morgan Reid, Director of Transplant Policy and Strategy (morgan.reid@kidney.org). Sincerely,

Kevin Longino
CEO and transplant patient

Paul Palevsky, MD
President