Michelle A. Josephson, MD, FASN
President-Elect, American Society of Nephrology
Roslyn B. Mannon, MD, FASN
Chair, American Society of Nephrology Policy and Advocacy Committee
On behalf of the American Society of Nephrology
1401 H Street, Suite 900, Washington, DC 20005

Written statement on Senate Finance Committee Hearing "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network"

Wednesday, August 3, 2022

On behalf of the 37 million Americans living with kidney diseases, thank you for your efforts to improve the United States transplant system. ASN seeks to transform transplant care and applauds the Senate Finance Committee for investigating shortcomings of the Organ Procurement Transplantation Network (OPTN).

"ASN believes a strong and equitable transplant system is essential to meet the needs of the more than 800,000 Americans living with kidney failure. While a kidney transplant is the optimal therapy for most people living with kidney failure, transplantation remains out of reach for too many people. ASN is deeply concerned with reports of technology failures from the OPTN contractor that are contributing to the immense organ discard rate and shortage of kidneys for transplantation. ASN reaffirms our call for the OPTN contract to be modernized."

"The more than 21,000 kidney health professionals who comprise ASN are committed to creating a world without kidney diseases, including by transforming transplant care. ASN commends the Senate Finance Committee for continuing to drive improvements in transplantation and stands in partnership to ensure all Americans who could benefit have access to this critical therapy," said ASN President Elect Michelle A. Josephson, MD, FASN in a press statement.

Of the more than 100,000 people currently on the transplant waiting list, there are nearly 90,000 people currently waiting to receive a kidney, the largest subset of any organ. Devastatingly, a national organ shortage means that 13 people die every day while on the kidney transplant waitlist.

ASN believes that transformations are needed across the transplant system in order to meet the growing need for kidney transplantation, including at the level of the OPTN. This statement focuses on 4 policy recommendations that address challenges related to the OPTN, including:

- Modernize the OPTN contract by separating the IT infrastructure into a distinct contract
- Address barriers to transplant access that promote or exacerbate inequities, including the use of race in the organ quality metric that guides allocation Kidney Donor Profile Index (KPDI)

- Streamline oversight of the U.S. transplant system by establishing an office of organ transplantation
- Elevate transplant patients as partners in care, including by improving transparency regarding organ offers

Modernize the OPTN contract by separating the IT infrastructure into a distinct contract

The OPTN is a quasi-governmental government agency responsible for establishing organ transplant and allocation policy, conducting oversight and enforcement of transplant programs and Organ Procurement Organizations (OPOs), and maintaining an IT infrastructure to support transplantation. The OPTN contract has been held by a single non-for-profit organization, the United Network for Organ Sharing (UNOS) since the contract was created in 1986.

UNOS maintains an IT infrastructure, which UNOS claims to be proprietary despite being developed under a federal contract with tax dollars and user fees, to support waitlisting, organ allocation, sharing of donor information and data capture for regulatory oversight. As revealed by the Washington Post, stakeholders in government have expressed repeated concerns over UNOS continued use of antiquated systems for data capture and collection with no validation tools or interoperability features. The stakeholders, including the White House U.S. Digital Service, noted deep issues with transparency when reviewed by the service as well as major security vulnerabilities. Efforts to modernize these systems have been slow and ineffective, with changes in policy such as new organ allocation schemes taking as long as a year or more to implement.

Further, data are collected from different parts of the transplant system at the expense and labor of transplant centers and OPO staff, and then returned back to transplant centers and OPOs in the form of well curated dashboards (for a fee for national datasets), while some free reporting tools exist, they are often clunky and lack the depth of information provided in paid reporting tools. Despite being established through taxpayer and user-fee supported funding, the Washington Post reports that UNOS claims ownership of the system and would charge the American taxpayer $55 million to purchase the current IT system should it ever lose the contract.

This arrangement is unique as other important responsibilities in transplantation, such as the statistical and analytical support provided by the Scientific Registry of Transplant Recipients (SRTR), are structured as an independent contract. It is no surprise that stakeholders ranging from the White House U.S. Digital Service to a bipartisan group of HHS technology officers to the National Academies of Science and Medicine have all called for the IT infrastructure responsibilities of OPTN to be separated into an independent and competitive contract. ***Separating the IT infrastructure portion of the OPTN contract would align with other federal contracting protocols, increase competition, and drive innovation.***

Address barriers to transplant access that promote or exacerbate inequity, including the use of race in the organ quality metric that guides allocation, Kidney Donor Profile Index (KPDI)

Kidney transplantation is the optimal therapy for most people living with kidney failure, yet kidney transplantation is not equally accessible for all Americans. For example, Black patients are less likely to be identified as transplant candidates, referred for evaluation to receive a pre-emptive transplant, and to complete the transplant evaluation. Black patients are also less likely

to have the preferred living donor and less likely to be placed on the waiting list, while also being more likely to receive lower quality kidneys regardless of the age of the patient and length on the kidney waitlist, and have poorer transplant graft survival for a multitude of reasons that may include difficulties in access to care – a cyclical and compounding struggle that is nearly impossible to defeat without real identification and solution to racism.

Many of the policies needed to establish equity in transplant require cooperation between multiple stakeholders in the private sector and across different government agencies. However, one improvement is squarely in the purview of the OPTN contractor: removing the use of race in metrics related to organ allocation.

Race does not have any physiological relationship with the function of a patient's kidney, yet clinical decision support tools such as the estimated Glomerular Filtration Rate equation (eGFR) have included race adjustor variables, systemically overestimating the kidney function of Black patients and leading to reduced access to transplantation. On June 27, 2022, OPTN finalized a policy to remove race as a variable from eGFR, following the recommendation of the American Society of Nephrology and National Kidney Foundation and citing concerns that the variable was leading to a 16% overestimation of kidney function among Black patients.

Despite this welcome decision, OPTN is still allowing a race adjustment in the Kidney Donor Profile Index (KDPI), with no public plans to cease their use. The KDPI estimates the relative risk of post-transplant kidney graft failure of organs obtained from a deceased donor. The KDPI includes a race variable, automatically assigning lower quality to kidneys obtained from Black donors independent of biological factors, arbitrarily reducing the supply of donated kidneys and effectively turning away the gift of life from Black donors. Analyses from SRTR have demonstrated that removing a race variable does not alter the equation's predictability of graft failure or patient survival. ***Race variables should be removed from tools assessing biological factors, including the organ quality metric that guides kidney allocation, the Kidney Donor Profile Index.***

Streamline oversight of the U.S. transplant system by establishing an office of organ transplantation

Oversight of the US transplant system is currently divided between the Centers for Medicare and Medicaid Services (CMS), who oversee transplant programs, and the Health Resources and Services Administration (HRSA), who oversee OPTN and OPO contractors. This split responsibility leads to gaps in oversight, confusion in navigating the transplant system, and a regulatory framework that does not elevate patients to be true partners in care.

One glaring example of this confusion is the use of financial means testing to evaluate a transplant recipient's eligibility to receive a transplant. In 2020, Congress passed the Comprehensive Immunosuppressive Drug Coverage Act, effectively ending the need for kidney transplant recipients to pay for immunosuppressive drugs out of pocket and a commonly used justification for financial screening.

Both transplant programs, regulated by CMS under the Conditions for Coverage, and the OPTN contractor, regulated by HRSA under the OPTN final rule mandate that patient selection (CMS) and organ allocation (HRSA) must ensure fair and non-discriminatory distribution of organs, yet financial criteria are still used to screen low-SES people from access to transplantation, even if the patient is otherwise healthy and a good transplant candidate.

Establishing a unified office of organ transplantation at HHS would enable transplant policy to be built around people in need of a transplant as opposed to being built around regulatory silos. Broadly, transplant policy should be aligned with the primary goal of increasing access to kidney transplantation to the maximum number of patients with kidney failure while improving longer term post-transplant outcomes (particularly among our younger recipients) and quality of life (particularly among older recipients where long-term survival may not be the paramount goal).

Currently, regulations across kidney care, including for dialysis facilities, transplant centers, and OPTN are not aligned and do not recognize the role of all in facilitating a smooth transition of care for patients. As a result, there are silos of care that occur in the nephrology clinic, dialysis unit, and the transplant center that increase challenges faced by patients in achieving optimal patient care. Establishing a single office of organ and transplant policy would better encourage patient-centered regulation instead of the current framework which focuses almost exclusively on short-term patient outcomes. This shift would improve communications across silos of care (dialysis units, referring nephrologists, and transplant centers), encourage transplant centers to provide increased and timely access to evaluation and related testing, and encourage greater communication about waitlisted candidates among transplant centers and current care teams ***Unifying oversight of the transplant system under a single office would ensure that patient-interest do not become lost in gaps of oversight.***

Elevate transplant patients as partners in care, including by improving transparency regarding organ offers

ASN believes that patients should be informed partners in their care, and most patients want more rather than less information about their care. Unfortunately, the current transplant system does not emphasize this principle: most patients are currently unaware of organ offers that are declined on their behalf by their care team. This is particularly concerning given research has shown that 85% of all kidneys are declined at least once, and that the 10,000 people who die per year on the transplant waitlist receive a median of 16 organ offers while waiting for an organ.

While real time notifications of organ offers are likely not feasible, practical, or desirable, asynchronous communication of these offers are a potential option for improving patient engagement and elevating patients as partners in their care. IT systems could be developed to facilitate local EHR communications and increase transparency and communication between people waiting for a transplant and the transplant care team. and

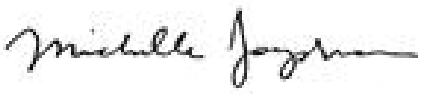
For example, informing patients at regular intervals (every three or six months) could help by improving communication between patients, transplant center and dialysis providers about patient preferences and priorities, and by helping patients appreciate the tradeoff between increased selectivity for organs and wait times for those organs.

Finally, it would be of considerable benefit for transplant centers to have effective tools to assess the implications of turning down an offer, just as much as patients need tools to assess the implications of accepting a higher risk kidney compared to remaining on the transplant waitlist. ***Above all, patients should be provided the opportunity to be true partners in their care, and transparency should be fostered in the transplant system to elevate patients to be informed decision makers wherever possible.***

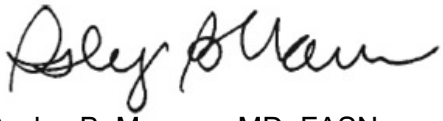
Conclusion

Again, thank you for addressing this high area of need in the transplant system. ASN stands ready to help address these challenges and transform transplant care into an accessible therapy for all Americans. Should you have any questions about this statement, please do not hesitate to contact Zach Kribs, ASN Manager of Congressional Affairs at zkribs@asn-online.org or 202-618-6991.

Sincerely,



Michelle A. Josephson, MD, FASN
ASN President-Elect



Roslyn B. Mannon, MD, FASN
Chair, ASN Policy and Advocacy Committee