NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016
212.889.2210

July 29, 2025

Re: Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx–New

Samantha Miller, HRSA Information Collection Clearance Officer
paperwork@hrsa.gov

cc:

Suma Nair, Associate Administrator, Health Systems Bureau (HSB), Health Services and Resources Administration (HRSA)
Dr. Raymond Lynch, Organ Transplantation Branch Chief, Division of Transplantation, HSB, HRSA
Brianna Doby, Branch Chief, Data and Analytics, Division of Transplantation, HSB, HRSA

Dear Samantha,

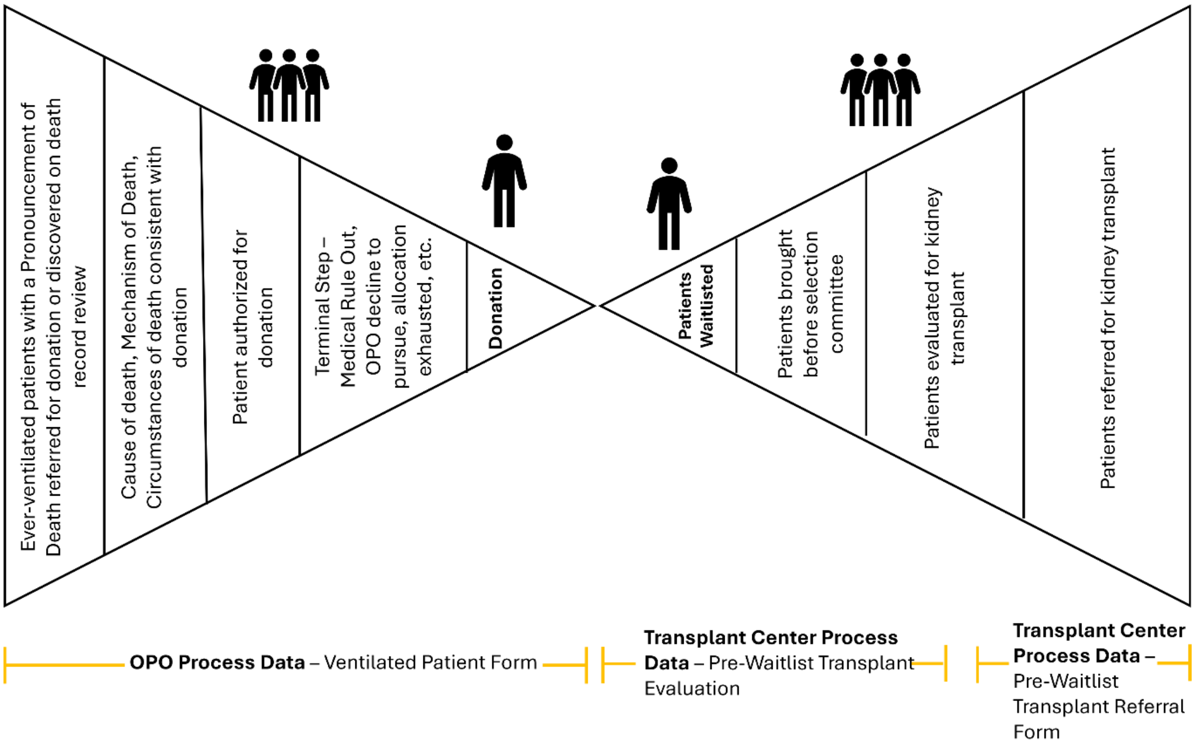
The National Kidney Foundation (NKF) is writing to express our strong commitment to the implementation of the three data collection instruments described in the Health Resources and Services Administration (HRSA) Secretarial Data Directive of February 2024, directing the Organ Procurement and Transplant Network (OPTN) to collect additional data on pre-waitlist and procurement practices.

Our nation's transplant system is undergoing a period of unprecedented scrutiny. Ensuring policymakers and the public have greater visibility into the processes that govern organ procurement (i.e., Organ Procurement Organization processes) and pre-waitlist transplant center processes are essential to restoring the public's trust in this fragile, but vital part of America's healthcare infrastructure.

Data to Inform Policy

The National Kidney Foundation (NKF) advances a robust agenda of material policy solutions in the service of the organization's overarching mission to ensure every person who needs a kidney transplant can access one. A pillar of NKF's support for the modernization of the Organ Procurement and Transplant Network (OPTN) is our hope for more comprehensive data to support solutions to some of patients' most pressing concerns about procurement and transplant: *is organ donation safe, did my donor receive safe, dignified, high-quality care, and why was I denied access to kidney transplant?*

Process data are essential for elucidating gaps in care delivery. Our transplant system has an obligation to every patient that touches it. As is clinically and ethically appropriate, patients are lost to attrition at many stages throughout procurement and pre-transplant processes. For example, in procurement, a patient may have his or her case closed because of a clinically appropriate medical rule-out. On the converse side of the process, a patient referred for a kidney transplant can have that referral closed out because of an active or recent cancer. The result is a winnowing of the populations that are referred for donation and kidney transplant until the relatively small proportion of the original population either donates or is waitlisted (Figure 1).



A key component of whole system accountability is making key steps in the procurement, donation, and transplant processes visible at the organization and transplant system levels. As described previously, some attrition from these processes is appropriate and necessary, a function of the population OPOs and transplant centers serve and the underlying infrastructure that supports the operations of these entities. However, ***not all attrition is patient-centered***. OPOs may not appear on-site for a referral, hospitals may inappropriately interfere with procurement, for example by blocking the OPOs approach for authorization, and transplant centers may close out referrals due to bias. Accountability for the system is contingent on understanding where these gaps persist and instituting policies that, over time, successfully close them.

The Ventilated Patient Form (VPF), Pre-waitlist Transplant Referral Form, and the Pre-waitlist Transplant Evaluation Forms are essential components of improving accountability because they provide insight into gaps in care delivery across our nation’s 257 transplant centers and 56 OPOs; that is, these instruments will provide visibility into system-wide heterogeneity in procurement and pre-waitlist processes. At this level of system-wide data availability, patterns in care delivery emerge, giving policymakers the public the opportunity to understand where these gaps are appropriate and where they are not and, in the latter case, where further accountability to patients and the public is necessary to assure the fairness and effectiveness of the U.S. transplant system. Once the forms have been implemented, we encourage the Division of Transplantation (DOT) to determine an avenue to support the release of these data to the public on a regular cadence.

Burden

All new data collection instruments will be implicated by resistance from the organizations required to report using them. Every transplant center in the country is affiliated with an academic medical center with a modern technology back-end. Virtually every OPO is supported by a procurement-specific electronic health record (EHR). We believe most, if not all, of the data elements across the three instruments are already being collected. For workflow purposes, OPOs already report data through the Death Notification Registration and Deceased Donor Death Referral (DDR). The DDR, the closest comparable form to VPF, must already be submitted 30 days after the end of the month in which a hospital reports a death to the OPO, or a death is identified by death record review. The DDR must be submitted for all imminent and eligible deaths in a DSA. A high performing OPO that is following up on all referrals in the DSA, made consistent with hospital regulations at 42 CFR 482.45 that require the hospital to notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died, should not experience markedly more burden than that associated with the DDR. Similarly, transplant centers already have workflows to support data reporting to the OPTN.

Notably, the OPTN contractor has developed numerous Application Programming Interfaces (APIs), including those to facilitate seamless DNR and DDR reporting for OPOs, and reporting of the transplant recipient registration (TRR) and transplant candidate registration (TCR), among other forms. We understand adoption of these APIs among OPTN members is low. Given the White House's focus on improving the free flow of data across health care organizations and the government, the timing is right to encourage transplant organizations to improve their digital functionality in the spirit of increasing transparency and trust in America's transplant system.

Restoring Trust

The processes of organ procurement and being waitlisted for a kidney transplant are fragile because they are policy issues of scarcity and subjectivity operating under the umbrella of the public's trust. The public trusts that registering to be an organ donor means they will be treated as patients and with the safety and dignity that choice deserves. People who seek access to kidney transplantation and their families are aware of the scarcity of organs; they understand that the wait for a kidney transplant can exceed five years and trust that the ecosystem of transplant stakeholders is working in concert to shorten the length of that wait. Before the wait begins, the process of simply being listed for a kidney transplant is opaque to patients, who put their trust in a process from which they can be removed without their knowledge or understanding.

Our transplant system is too important to leave OPOs and transplant centers operating in the dark. The public will trust a high-performing system where performance is validated by transparent and accessible data. We encourage the Department to act expeditiously to implement the data collection instruments described in the Public Comment Request. Accountability and trust cannot wait.

Sincerely,

K Campbell

Kevin Longino
CEO and Transplant Patient

Kirk Campbell, MD
President