



December 20, 2024

The Honorable Carol Johnson  
Administrator  
Health Resources and Services Administration  
Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

Information Collection Clearance Officer  
Room 14NWH04  
Health Resources and Services Administration  
Department of Health and Human Services  
5600 Fisher Lane  
Rockville, MD 20857

**Re: Public Comment Request; Information Collection Request Title: Data System for Organ Procurement and Transplantation Network**

Dear Administrator Johnson,

On behalf of Kidney Care Partners (KCP), I want to convey our appreciation for the Administration's efforts to develop and implement system-wide policy changes to improve organ donation and organ transplantation. We are pleased to have the opportunity to provide comments on the "Public Comment Request; Information Collection Request Title: Data System for Organ Procurement and Transplantation Network" (ICR request).

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD). Our mission is to involve patient advocates, care professionals, providers and manufacturers to ensure:

- Individuals living with kidney diseases receive optimal care;
- Individuals living with kidney diseases are able to live quality lives;
- Dialysis care is readily accessible to all those in need; and
- Research and development lead to enhanced therapies and innovative products.

The ICR request seeks comments about requiring new data collection forms related to candidates listed in the OPTN organ transplant waiting list that would allow a transplant center to add, change, or remove candidates from the OPTN waiting list after a completed patient evaluation. The request also seeks comments on revising existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.

KCP's Transplant Work Group, which is comprised of patient advocates, organ donation and transplant experts, physicians, dialysis facilities, manufacturers, and other health care

professionals, developed our response to the ICR request. KCP recognizes that the optimal treatment for most individuals living with kidney failure is a kidney transplant; yet the number of organs available falls far short of meeting the need of those hoping for a transplant. We appreciate the HRSA's efforts related to the OPTN Modernization Initiative; the compliance with federal law; the public reporting on the status of organ donation, procurement, and transplantation in the United States; the availability of data to support research and government agencies in the area of organ transplantation; and the performance of public health surveillance related to organ transplants.

In response to the specific data collection outlined in the ICR request, KCP members are concerned that the estimated increase in reporting burden forth in the preamble of 203,937.21 hours may undercut the goals of the initiative. It appears this estimate was based on exclusively manual reporting. KCP urges HRSA to implement this data collection using batch reporting, and to work towards ensuring that option is available for all transplant centers.

We have heard concerns about manual entry when batch reporting may not be an option under some electronic health record (EHR) systems. With the recent passage of legislation reforming the organ procurement system, it may be appropriate for HRSA to ask the new contractors tasked with creating the new information technology platforms to ensure the creation of the necessary API interfaces and to address challenges transplant centers have identified with not all EHR systems supporting the changes. Moreover, this step could be expanded to require interoperability between transplant center and dialysis facilities and nephrologists to support communication about waitlist status across patients' primary care teams as well.

Moreover, we are concerned that not every EMR may use the exact same data elements as the proposed data collection for. While a limited issue that can be resolved, either at a local IT level or at the EMR vendor level, but time will need to be allowed for these changes to be implemented where needed before mandatory data collection begins. If not addressed, the problems that plague current data collection efforts will remain unresolved. Inconsistencies in the data will thwart HRSA's goals outlined in the ICR request.

KCP agrees that the goals of the new information collection forms are important, but we are concerned that the data must be collected via batch submissions to ensure accuracy of the information provided, and in a way that protects patient privacy/confidentiality.

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KCP appreciates the opportunity to provide comments on the ICR request. We look forward to working with HRSA as it implements the recent legislative reforms to improve the organ procurement and transplantation system and refine the data collection efforts to support patients and the transplant community. We share the goal of improving access to transplant in the United States. If you have questions about our comments or would like to talk with our members, please do not hesitate to contact our counsel in Washington, Kathy Lester.

Sincerely,

A handwritten signature in black ink, reading "Mahesh Krishnan". The signature is fluid and cursive, with the first name "Mahesh" and last name "Krishnan" clearly distinguishable.

Mahesh Krishnan MD MPH MBA FASN  
Chairman  
Kidney Care Partners

**Appendix: KCP Members**

Akebia Therapeutics  
American Kidney Fund  
American Nephrology Nurses' Association  
American Society of Nephrology  
American Society of Pediatric Nephrology  
Ardelyx  
Atlantic Dialysis  
Baxter  
Cormedix  
CSL Vifor  
DaVita  
Diality  
Dialysis Care Center  
Dialysis Patient Citizens  
Fresenius Medical Care  
GlaxoSmithKline  
Greenfield Health Systems  
Kidney Care Council  
NATCO  
Nephrology Nursing Certification Commission  
Renal Healthcare Association  
Renal Physicians Association  
Renal Support Network  
The Rogosin Institute  
U.S. Renal Care  
Unicycive