



October 9, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0937-AA13: Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act

Dear Secretary Becerra,

On behalf of the nearly 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the “Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act” Proposed Rule (Proposed Rule). In brief, KCP strongly supports the proposal to eliminate the requirement that kidney and liver transplants of HIV positive organs to recipients with HIV be conducted as clinical research and under the approval of an Institutional Review Board (IRB).

The best therapeutic option for individuals living with kidney failure is a kidney transplant. Yet, the vast majority of people with kidney failure do not have access to a transplant. The primary reason is that for the tens of thousands of patients on kidney transplant waitlists, there are only a few thousand organs available for transplant. In 2018, for example, USRDS reports that there were 78,675 on the waiting list for kidney transplants¹, but as the preamble of the Department’s 2019 “Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities” noted, only 3,755 kidneys were recovered from deceased donors.² USRDS also reports that “[a]mong patients listed for a deceased donor kidney transplant between 2009-2013, the percentage receiving a transplant, including from a living donor, was 19.5 percent after 1 year, 37 percent after 3 years, and 47.5 percent after 5 years.”³ The kidney transplant system fails to support the vast majority of people for whom it is their best option.

Given the unmet need for kidneys, it is important that the transplant community and federal government support policies to increase the number of available organs. KCP agrees that clinical data outlined in the preamble of the Proposed Rule supports efforts to expand

¹United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. Ch. 1. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

²86 *Fed. Reg.* 68594, 68596.

³*Supra*, note 1.

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access to kidneys. While we understand that the rejection rates of transplanting kidneys with HIV to individuals with HIV in some of the studies were higher than transplanting kidneys without HIV, the use of immunosuppressive regimens can reduce this risk.⁴

We also believe that this proposed modification would support the Administration's efforts to address health disparities. As CMS has recognized, the Medicare ESRD patient population is disproportionately low-income and black. According to the U.S. Renal Data System (USRDS), 18.9 percent of prevalent ESRD patients were dually eligible for Medicare and Medicaid in 2021.⁵ In 2019, 22.3 percent of prevalent ESRD patients were dually eligible,⁶ while more than a quarter of all ESRD prevalent patients were dually eligible in 2011.⁷ As the Assistant Secretary for Planning and Evaluation (ASPE) has reported dual eligibility status is one of the most significant predictors of negative health outcomes.⁸ These patients often present with greater medical complexity than their counterparts. Black patients experience median wait-times once on a waitlist twice that of White patients.⁹ Eliminating the research and IRB requirements for kidney and live HOPE Act transplants would be an important step to help reduce the barriers to accessing transplant for people of color.

In terms of the request for comments on the Secretary's direction to the OPTN, KCP defers to health care professionals as to the content of such directions. We urge HHS to make sure that the final policies do not create additional barriers or lead to unintended consequences that make it more difficult for individuals to access these organs.

KCP appreciates the opportunity to provide comments and is pleased with the Administration's efforts to reduce unnecessary barriers kidney transplants.

Sincerely,



Mahesh Krishnan MD MPH MBA FASN

Chairman

Kidney Care Partners

cc: Frank Holloman, Director of Transplantation, HRSA

⁴89 Fed. Reg. 74174, 74178.

⁵USRDS. Annual Data Report. Ch. 9 "Healthcare Expenditures for Persons with ESRD." (2023). Available at: <https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd>.

⁶*Id.*

⁷*Id.* at Chart 9.4b.

⁸Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: <https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicare-value-based-purchasing-programs>.

⁹*Supra*, note 1 (Figure 6.9 by race)

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
Centers for Dialysis Care
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