



October 15, 2024

Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Rachel L. Levine, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Submitted electronically

Re: ID HRSA-2024-0001

Dear Administrator Johnson and Assistant Secretary Levine:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the September 2024 proposal to related to the implementation of the HIV Organ Policy Equity (HOPE) Act of 2013. ASN is committed to creating a world without kidney diseases, including by continuing to drive improvements in transplantation and maximizing access to this critical therapy for all Americans who could benefit.

ASN strongly supports the proposal to lift the current research and Institutional Review Board (IRB) requirements for HOPE Act kidneys.

More than 10 years ago, ASN advocated vociferously for the passage of the HOPE Act and remains a staunch supporter of the objectives of the law.ⁱ More recently, ASN supported the 2022 recommendation from the HHS Advisory Committee on Blood and Tissue Safety and Availability to proceed with removing the research and IRB requirements. ASN appreciates and commends the HOPE In Action Consortium, the OPTN, the National Institutes of Health, and the Department of Health and Human Services (HHS) to conduct and study HOPE Act-enabled transplants (HIV positive organs to HIV positive recipients) over the last decade. Their crucial work makes possible the expansion of access to HOPE Act-enabled transplants to many more Americans nationwide.

The society's comments in this letter focus on HOPE Act kidneys, as nephrology care is the focus of ASN's efforts. 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. Of the more than 90,000 people waiting to receive a kidney, 13 die every day.ⁱⁱ While a kidney transplant is the optimal therapy for most people living with kidney failure, transplantation remains out of reach for too many people. Full implementation of the HOPE Act will make a meaningful improvement in access to care for more Americans with kidney failure both living with and without HIV.

The promise of the HOPE Act—that waitlisted Americans with HIV could opt to receive an HIV+ organ, potentially reducing both their wait time and the wait time for individuals without HIV awaiting a transplant—is supported by the extensive research conducted over the last decade, as presented in the proposed rule. For the reasons HHS outlined in the proposed rule, summarized below, ASN strongly supports the Secretary’s recommendation that adherence to research and IRB requirements as a requirement for kidney transplants from donors with HIV is no longer warranted. Furthermore, ASN believes that removing these requirements could lead to an increase in the number of kidney and liver transplants performed between HIV-positive individuals.

Demonstrated safety: As outlined in the proposed rule, with over 300 HOPE Act transplants conducted and studied in recipients with HIV under the OPTN HOPE Act variance, no patient safety concerns have been identified, and no HOPE Act research has been halted, paused, or substantially amended to address recipient safety concerns.ⁱⁱⁱ Crucially, there are no recorded accidental or inadvertent transmission events in the data reviewed by the OPTN, and no reports have been made to the OPTN of safety issues regarding HOPE Act transplants among OPO, hospital, or transplant center personnel or in patients, in donor hospitals, or transplant hospitals.

ASN is heartened by this robust body of safety findings, which corroborate earlier research in other countries that pioneered HIV positive organ transplantation and that helped to inspire enactment of the HOPE Act in the United States. The society also notes that routine, ongoing OPTN patient safety reporting mechanisms and monitoring will provide a further backstop to identify any safety issues with HOPE Act transplants moving forward, though such events are unexpected based on the extensive research described in the proposed rule. Two ongoing NIH-funded trials will continue to provide valuable information about HOPE Act kidney transplants, adding to the important body of knowledge about HIV positive transplants.

Additionally, given the relatively limited number of living donor HOPE Act kidney transplants that have been performed during the last decade in the United States and short follow up, ASN encourages identification of a mechanism for monitoring long-term safety of these unique HIV+ living donors over the coming years, through MPSC or otherwise, to ensure their outcomes align with those of non-HIV-infected living donors.

Advancing health equity: Advancing health equity is a top ASN priority. As HHS notes, gay, bisexual and transgender people have disproportionately high rates of HIV relative to their representation in the general population. Black and Hispanic populations are both disproportionately affected by kidney failure and disproportionately affected by HIV.^{iv} ASN agrees with HHS’ assessment that full HOPE Act implementation will increase access to kidney transplantation to people with kidney failure who are HIV positive, an outcome that is consistent with both ASN and HHS’ commitment to equity.

Improved access for a vulnerable population: People with kidney failure and HIV have higher pretransplant mortality rates than people with kidney failure who are not also living with HIV. As HHS outlined, studies of HOPE Act transplants clearly demonstrate a survival benefit of transplanting kidneys from donors with HIV to recipients with HIV. ASN concurs that HOPE Act kidney transplants have the potential to mitigate disparities for a vulnerable population that faces higher waitlist mortality.

The finding that 70 percent of HOPE Act recipients received a kidney transplant during one 4.5 year study period versus 43 percent of non-HOPE Act transplant candidates suggests the benefits of HOPE Act kidneys could substantially increase access for eligible recipients.^v

Together with the finding in this study that people who received an HIV positive kidney through a HOPE Act trial had much shorter wait times (median 10.3 months versus 60.8 months) and overall higher likelihood (3.3 times greater) of transplantation, the availability of kidneys from donors with HIV clearly has the potential to increase access to transplantation among people with HIV.^{vi}

Shortened waitlist: As some people who are eligible to receive HOPE Act kidneys elect to do so, they will access a pool of kidneys that were previously unusable. HOPE Act implementation will effectively grow the pool of available kidneys in the United States. As certain eligible candidates choose to receive HOPE Act kidneys, they are removed from the kidney waitlist, effectively shortening the wait list for individuals without HIV who are currently waiting for a transplant. Reducing wait times for kidneys and increasing utilization of the available supply of kidneys aligns with numerous other ongoing HHS priorities, including the proposed Increasing Organ Transplant Access (IOTA) implementation of the *Securing the U.S. OPTN Act* to improve system efficiency.

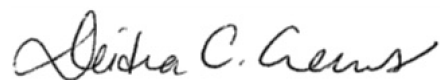
Expanded geographical access to HOPE Act transplants: HHS outlines its expectations that by eliminating the requirement that HOPE Act kidney transplants are conducted in the research context, a larger number of transplant centers nationwide will be able to conduct HOPE Act transplants than the limited number that participated in the pioneering HOPE Act transplants under the research protocols. Under research protocols, only approximately 30 of the 231 active kidney transplant programs in the U.S. conducted HOPE Act kidney transplants.^{vii,viii} Should HHS finalize the proposal to lift the IRB and research requirements, more transplant centers can offer these transplants in more geographies, and more Americans will have HOPE Act kidneys as an option to consider with their local care teams. While not every program will necessarily opt to offer HOPE Act transplants, creating the option is a crucial step towards increasing access.

Conclusions

In sum, ASN agrees that removing the IRB and research requirements for HOPE Act transplants will enable more transplantation of HIV positive kidneys into recipients with HIV, thereby expanding opportunities for people with HIV and kidney failure broadly; ASN firmly supports the Secretary's recommendation to do so in this proposed rule. ASN also looks forward to providing comments to the OPTN supporting this implementation through a likely future proposed revision to relevant OPTN policies, as outlined in this proposed rule.

To discuss these recommendations further, or if ASN can provide any additional information, please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

ⁱ ASN Statement of Support for the HIV Organ Policy Equity Act. April 2013. https://www.asn-online.org/policy/webdocs/asn_statement_of_support_for_hope_act_april_25.pdf

ⁱⁱ OPTN National Data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#> Accessed Monday, September 30, 2024.

ⁱⁱⁱ Cooper M. "OPTN Letter to Secretary Becerra on the HOPE Act." October 2021.

<https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf>

^{iv} Centers for Disease Control and Prevention. HIV Surveillance Report, 2021; vol. 34.

<https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. May 2023.

^v Motter JD, et al for the HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. March 2024.

^{vi} *Ibid.*

^{vii} Transplant Centers Approved for HOPE Act. OPTN. May 31, 2024.

<https://optn.transplant.hrsa.gov/media/ex3bmasx/hope-act-hospitals.pdf> Accessed Monday, September 30, 2024.

^{viii} 7 Years of HOPE. United Network for Organ Sharing. November 2022. <https://unos.org/news/in-focus/7-years-of-hope/> Accessed Thursday, October 3.