



April 22, 2025

Stephanie M. Pouch, MD
Chair
Organ Procurement and Transplantation Committee
Ad Hoc Disease Transmission Advisory Committee
1365 Clifton Road NE
Atlanta, GA 30322

Submitted electronically

Re: Public Comment Proposal Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates

Dear Dr. Pouch:

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 March 2025 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 modify Organ Procurement and Transplantation Network (OPTN) policy to align with current U.S. Department of Health and Human Services (HHS) policy to remove research requirements for transplantation of kidneys, livers, and liver-kidneys from donors with HIV to recipient individuals living with HIV.

A kidney transplant is the optimal therapy for most people living with kidney failure, yet 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 those living with and without HIV.

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 as well as the proposed 2024 HHS proposed rule to lift research requirements for HOPE Act transplants.ⁱⁱ ASN commends the committee and the OPTN for taking this step to align OPTN policy with other recently-enacted HHS policy to allow the expansion of access to HOPE Act-enabled transplants to many more Americans nationwide.

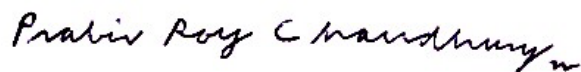
ASN supports the proposal to align OPTN policy and systems to comply with the amended OPTN Final Rule and NIH Final Notice so that:

- Transplants of kidneys, livers, and liver-kidneys from donors with HIV to recipients living with HIV no longer require compliance with NIH research protocols or participation in an OPTN variance;
- Transplants of kidneys, livers, and liver-kidneys from donors with HIV to recipients living with HIV include adequate patient safety measures;
- Non-kidney and non-liver transplants of organs from donors with HIV to recipients with HIV still reflect requirements regarding current NIH research criteria and participation in the OPTN HOPE Act variance;
- Language in OPTN policy is updated to refer respectfully and consistently to individuals with HIV; and
- OPTN requirements are clearly articulated and support patient safety.

As outlined in the OPTN proposal and similar recent prior policy change proposals, the promise of the HOPE Act—that waitlisted Americans living with HIV could opt to receive an HIV positive 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. ASN continues to believe that adherence to research and IRB requirements as a requirement for kidney transplants from donors with HIV is no longer warranted—and that the removal of these requirements as proposed—could lead to an increase in the number of kidney and liver transplants performed between HIV-positive individuals.

To discuss ASN’s support for this proposed OPTN policy change, please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org.

Sincerely,



Prabir Roy-Chaudhury, MD, PhD 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 ASN comments on HOPE Act implementation. October 2024. https://www.asn-online.org/policy/webdocs/24.10.15_DCC_FINALHOPEActImplementationComments.pdf