

Biden-Harris Administration Issues Proposed Rule to Expand Access to Life-Saving Organs for People with HIV

The proposal would remove clinical research requirements for transplantation of kidneys and livers from donors with HIV.

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Today [September 12], the Department of Health and Human Services (HHS), through the Office of the Assistant Secretary for Health (OASH) and the Health Resources and Services Administration (HRSA), announce a Notice of Proposed Rulemaking (NPRM) to amend the regulations implementing the National Organ Transplant Act of 1984.

“All across this country there are HIV-positive Americans who need an organ transplant and HIV-positive Americans who are ready and willing to donate. Unfortunately, the process of approving those transplants is too slow and too few transplant centers participate due to burdensome requirements, resulting in unnecessary suffering for all involved,” said HHS Secretary Xavier Becerra. “Our new policy removes these requirements for HIV-positive kidney and liver transplants and will expand access to organ transplantation for people with HIV and increase overall transplant volumes for all Americans irrespective of their HIV status. This is another important step by the Biden-Harris Administration to reduce stigma and health disparities around organ transplantation, and lower health care costs for Americans.”

The proposed rule change, if finalized, would remove clinical research and institutional review board (IRB) requirements for transplantation of kidney and livers from donors with human immunodeficiency virus (HIV) to recipients with HIV. The proposed rule, Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act, is based on rigorous analysis of clinical data.

The HOPE Act, signed into law on November 21, 2013, allows organs from donors with HIV to be transplanted into candidates with HIV, under research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants. Participating hospitals conduct transplants under IRB-approved research protocols conforming to the National Institutes of Health (NIH) standards titled “HOPE Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV.”

This proposed rule applies to HOPE Act liver and kidney transplants. There is significantly less data available on HOPE Act transplants of other organs, making it difficult to assess the safety and outcomes of other HOPE Act transplants. In tandem with this proposed rule, the NIH intends to convene a working group to revisit its research criteria for other organs for HOPE Act transplants, with the goal of streamlining research requirements and continuing to build an evidence base of outcomes data on HOPE Act transplants of organs other than livers and kidneys.

If the proposed rule is finalized, HHS expects this rule will allow a larger number of transplant centers to conduct HOPE Act kidney and liver transplants and will help reduce the stigma and health disparities associated with HIV.

Public comments on the NPRM are due 30 days after publication of the NPRM in the Federal Register on October 15, 2024, at 11:59 PM ET. The NPRM may be viewed or downloaded at: [Federal Register: Public Inspection: Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act](#).

The proposed HHS rule is yet another step by HHS to improve access to care and social services for people with HIV, as well as expand access to organ transplants and [address systemic issues](#) such as inequities in access to transplants, conflicts of interest, and system reliability issues.

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