

VIA ELECTRONIC FILING — <http://www.regulations.gov>

October 2, 2024

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Secretary Becerra:

The Organ Procurement and Transplantation Network (OPTN) would like to thank HHS for the opportunity to comment on your proposed rule: *Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act* (Document ID HRSA 2024-001) that would remove clinical research and institutional review board (IRB) requirements for kidney and liver transplants of organs with human immunodeficiency virus (HIV) into persons living with HIV.

The OPTN fully supports the Secretary's determination that the current research and IRB requirements are no longer warranted for kidney and liver transplants performed under the HOPE Act. We appreciate this action following an OPTN recommendation provided in 2021¹. Increasing transplants and reducing the number of individuals waiting for a lifesaving organ continues to drive the work of the OPTN. The proposed rule change will permit all transplant programs to perform HOPE Act kidney and liver transplants, thereby increasing transplant opportunities for more individuals living with HIV and expanding equity for underserved populations.

The OPTN had recommended and originally made public comment on the *Fifty Sixth Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Meeting, Written Public Comment – November 17, 2022* to support removing National Institutes of Health (NIH) Research Criteria and IRB requirements for all organs². As noted in the current background statement for the proposed rule, the OPTN reviewed data safety monitoring board (DSMB) data reports from five years covering more than 300 HOPE Act transplants, and no DSMB identified any patient safety concerns. In addition, as noted in the proposed rule, no reports have been made to the OPTN of safety issues regarding HOPE Act transplants among

¹ OPTN, Letter to U.S. Health and Human Services Secretary Xavier Becerra, October 29, 2021.

² U.S. Department of Health and Human Services "Fifty-Sixth ACBTSA Meeting: November 17, 2022 - Written Public Comments", available at: <https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2022-11-17/written-public-comments/index.html> (accessed September 20, 2024).

organ procurement organization (OPO), hospital, or transplant program personnel or in patients, in donor hospitals, or in transplant hospitals³.

Through public comment, the OPTN shared concerns that retaining the current NIH Research Criteria would continue to perpetuate inequities and disparities in HOPE Act organ program development and negatively impact access to organs for persons living with HIV in need of a non-kidney or non-liver transplant. The OPTN supports the proposed rule to have NIH lead revisions to the Research Criteria. The OPTN is willing to collaborate with the NIH in these efforts to maintain the strong patient safety record while actively seeking to reduce burdens that may be slowing the establishment of non-kidney and non-liver programs. As of September 26, 2024, there are two approved heart transplant programs that have performed three heart transplants under the HOPE Act⁴.

Currently the OPTN governs all HOPE Act transplants under a specific OPTN policy variance⁵. OPTN policy changes will need to be proposed to align with the forthcoming final rule and, as approved, would govern kidney and liver transplants from donors with HIV to candidates living with HIV outside of the current specific variance. Non-kidney and non-liver transplants would remain under the HOPE Act OPTN policy variance which may also need to be amended to be consistent with the forthcoming final rule. OPTN oversight is routinely provided through post-implementation evaluations conducted at various intervals and reviewed by OPTN Committees as part of standard process for all policy changes. In addition, policy variances are evaluated annually. OPTN policy variances may be amended, extended, or terminated at any time by the OPTN Board of Directors⁶.

The OPTN structure and outcome data collected are sufficient in their current state to provide oversight for all organs. We note that the stated 15-month timeline for the OPTN to develop, share, and approve policy changes can be accomplished. The time frame for implementation, however, may be impacted and might need to be extended if the finalized rule requires additional data collection. Any data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule are collected through federal government Office of Management and Budget (OMB) approved data collection forms and therefore are subject to its approval process under the Paperwork Reduction Act of 1995.

Overall, the OPTN welcomes the Secretary's direction to revise its standards of quality as required by the HOPE Act. This will not jeopardize patient safety and will allow more individuals living with HIV to receive the life-saving organs they need and utilize organs that may otherwise go unrecovered or unused. The

³ U.S. Department of Health and Human Services, "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act," *Federal Register* Vol. 89 No 1777 (September 12, 2024): 74176, <https://www.govinfo.gov/content/pkg/FR-2024-09-12/pdf/2024-20643.pdf>.

⁴ Organ Procurement and Transplantation Network (OPTN) Data as of September 26, 2024.

⁵ OPTN, *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (Effective Date: 9/3/2024).

⁶ OPTN, *Policy 1.3: Variances* https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (Effective Date: 9/3/2024).

OPTN will continue to ensure patient safety is maintained as access to transplant under the HOPE Act is expanded.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Formica". The signature is fluid and cursive, with a large initial "R" and "F".

Richard Formica, MD
President, OPTN Board of Directors