sentence of Rule 3D .0535(f),[5] and in Rule 3D .0535(c) and (g), is proposing to incorporate only the statements that each paragraph ''is not included in Forsyth County's portion of the State Implementation Plan.'' [6] EPA has made and will continue to make these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The FCEAP did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this proposed action. Due to the nature of the proposed action being taken here, this proposed action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this proposed action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for communities with EJ concerns.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 6, 2024.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

[FR Doc. 2024–20666 Filed 9–11–24; 8:45 am]

BILLING CODE 6560–50–P

[5] The July 14, 2022, local effective version of the last sentence of Rule 3D .0535(f) contains a change that incorporates a reference to regulations not approved into the SIP. If EPA takes final action to approve the November 28, 2022, SIP revision, the Agency will update the SIP table at 40 CFR 52.1770(c) to reflect the retention of the September 14, 1998, version of the aforementioned sentence.

[6] If EPA takes final action to approve the November 28, 2022, SIP revision, the SIP-approved version of Rule 3D .0535(c) will read, ''(Paragraph (c) is not included in Forsyth County's portion of the State Implementation Plan.),'' and the SIP-approved version of .0535(g) will read, ''(Paragraph (g) is not included in Forsyth County's portion of the State Implementation Plan.).'' The Agency would update the SIP table at 40 CFR 52.1770(c) to reflect this fact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

RIN 0937–AA13

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

AGENCY: Office of the Assistant Secretary for Health (OASH) and Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to amend the regulations implementing the National Organ Transplant Act of 1984, as amended (NOTA), to remove clinical research and institutional review board (IRB) requirements (''research and IRB requirements'') for transplantation of kidney and livers from donors with human immunodeficiency virus (HIV) to recipients with HIV. As allowed by the HIV Organ Policy Equity (HOPE) Act, the Secretary of HHS proposes to determine that participation in such clinical research should no longer be a requirement for transplantation of HIV positive kidneys and livers from donors with HIV to recipients with HIV. This proposed rule serves as publication of the Secretary's proposed determination and proposes to amend the regulations to reflect this determination. Consistent with NOTA and current regulatory requirements, the Secretary's proposed determination and the proposed corresponding regulatory revision, if finalized, will necessitate that the Organ Procurement and Transplantation Network (OPTN) adopt and use standards of quality concerning kidneys and livers from donors with HIV, as

directed by the Secretary, consistent with NOTA and in a way that ensures the revised requirements for transplantation of such organs will not reduce the safety of organ transplantation.

DATES: Comments on this notice of proposed rulemaking should be received no later than October 15, 2024.

ADDRESSES: You may send comments, identified by Document ID HRSA–2024–0001, to the Federal eRulemaking Portal: *https://www.regulations.gov.* For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

In accordance with 5 U.S.C. 553(b)(4), a summary of this rulemaking may be found in the docket for this rulemaking at *www.regulations.gov* [Document ID HRSA–2024–0001].

FOR FURTHER INFORMATION CONTACT: Frank Holloman, Director, Division of Transplantation, Health Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W63, Rockville, MD 20857; by email at *donation@hrsa.gov;* or by telephone (301) 443–7577.

SUPPLEMENTARY INFORMATION:

I. Public Participation

All interested parties are invited to participate in this rulemaking by submitting written comments and supportive data that should be considered. HHS also invites comments that relate to the economic, legal, environmental, or federalism effects that might result from this proposed rule. Comments that will provide the most assistance to HHS in finalizing the rule will reference a specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authority that supports such recommended change.

Instructions: If you submit a comment, you must include the agency name and the Document ID HRSA–2024–0001 for this rulemaking. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make to HHS. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Docket: For access to the docket and to read background documents or comments received, go to *https://regulations.gov,* referencing Document ID HRSA–2024–0001. You may also sign up for email alerts on the online docket to be notified when comments are posted or a final rule is published.

II. Background and Purpose

A. HHS Oversight of Organ Allocation and Transplantation

Within HHS, HRSA is responsible for overseeing the operation of the nation's OPTN, including assisting in the equitable allocation of donor organs for transplantation. 42 U.S.C. 274(b)(2)(D). The allocation of organs is guided by the OPTN in accordance with NOTA and with the HHS regulations governing the operation of the OPTN in 42 Code of Federal Regulations (CFR) part 121. The OPTN is also charged with developing policies on many subjects related to organ donation and transplantation, which include establishing standards of quality pertaining to organs procured for use in transplantation. 42 U.S.C. 274(b)(2)(E). In addition to ensuring the efficient and effective allocation of donor organs through the OPTN, HHS supports efforts to increase the number of transplants performed in the United States.

B. HOPE Act Requirements and Implementation

In 1988, NOTA was amended to prohibit the transplantation of organs from donors with HIV, referring to HIV as the etiologic agent for acquired immunodeficiency virus or AIDS. Until 1997, a total of 32 kidney transplants were performed in recipients with HIV, all with organs from donors without HIV.[1] Advances in antiretroviral therapies (ART) have now made it possible for individuals with HIV to live longer and with fewer complications from the virus. Following the success of pioneering transplants occurring outside the United States of organs from donors with HIV to recipients with HIV,[2] interest in developing specialized HIV transplant programs grew domestically.[3]

The enactment of the HOPE Act in 2013, Public Law 113–51, amended NOTA to eliminate the prohibition in the United States on transplantation of organs from persons with HIV, allowing transplantation of these organs if certain requirements are satisfied. Under the HOPE Act, organs from donors with HIV may be transplanted only in recipients living with HIV prior to receiving such an organ. 42 U.S.C. 274(b)(3)(A). Further, the HOPE Act requires that transplants of HIV-positive organs occur only in recipients with HIV who are participating in IRB-approved research protocols that adhere to certain criteria, standards, and regulations. 42 U.S.C. 274(b)(3)(B)(i). However, the Secretary may lift the research and IRB requirements if the Secretary has determined that participation in such clinical research, as a requirement for such transplants, is no longer warranted. 42 U.S.C. 274(b)(3)(B)(ii).

The HOPE Act outlines the process by which the Secretary may make such a determination under 42 U.S.C. 274(b)(3)(B)(ii). Specifically, the Secretary must routinely review the results of clinical research, in conjunction with the OPTN, to determine whether the results warrant revision of the OPTN standards of quality regarding organs from donors with HIV. If the Secretary determines that those standards of quality should be revised, the Secretary must direct the OPTN to revise the standards. 42 U.S.C. 274f–5(c)(2). The Secretary is also required to revise the regulatory provision implementing the HOPE Act, 42 CFR 121.6, upon determining that revisions to the OPTN standards of quality are warranted. 42 U.S.C. 274f–5(c)(3).

HRSA published a final rule implementing the HOPE Act on May 8, 2015. 80 FR 26464.[4] The 2015 rule amended 42 CFR 121.6 to permit transplants of organs from donors with HIV in accordance with the HOPE Act requirements.

The HOPE Act also directs the Secretary to develop and publish criteria for the conduct of research relating to transplantation of organs from donors with HIV into persons who

[1] Werbel WA, Durand CM. Solid Organ Transplantation in HIV-Infected Recipients: History, Progress, and Frontiers. Curr HIV/AIDS Rep. 2019 Jun;16(3):191–203.

[2] Muller E, Barday Z, Mendelson M, Kahn D. HIV-Positive to HIV-Positive Kidney Transplantation—Results at 3 to 5 Years. New England Journal of Medicine. 2015 Feb 12;372(7):613–620.

[3] Botha J, Fabian J, Etheredge H, Conradie F, Tiemessen CT. HIV and Solid Organ Transplantation: Where Are we Now. Curr HIV/AIDS Rep. 2019 Oct;16(5):404–413.

[4] **Federal Register**. Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act. 2015 May:80 FR 26464. *https://www.federalregister.gov/documents/2015/05/08/2015-11048/organ-procurement-and-transplantation-implementation-of-the-hiv-organ-policy-equity-act.*

are living with HIV before receiving an HIV-positive organ. 42 U.S.C. 274f–5(a). Subsequent to publication of the 2015 rule implementing the HOPE Act, NIH published the *Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV,* on November 25, 2015. 80 FR 73785.[5] The NIH Research Criteria were developed by an HHS working group of entities involved in organ transplantation, with input from multiple stakeholders.

In general, the NIH Research Criteria include safeguards designed to protect both donors and recipients, as well as healthcare providers at Organ Procurement Organizations (OPOs), and transplant centers. Specifically, and in addition to the requirements in established OPTN transplant policies, donors with HIV must not have evidence of opportunistic infections and recipients must have a stable CD4+ T-cell count and established HIV suppression and control on effective ART. The study team must describe the anticipated effective HIV treatment plan and ART regimen for patients receiving an organ with a potentially different HIV strain. Antiretroviral drugs suppress viral replication; however, HIV may develop resistance to a specific drug necessitating a different medication regimen to maintain effectiveness.[6] Transplant hospitals conducting HOPE Act operations are required to have expertise in transplants provided to recipients with HIV. OPOs are required to have procedures in place to address working with families of deceased donors who lived with HIV and a biohazard plan to address viral exposure and potential transmission. Finally, the Research Criteria establish uniform outcome measures that must be incorporated in the research design so that data on HOPE Act transplants can be analyzed consistently and data collection is harmonized to inform future implementation of the HOPE Act.

Publication of both the final rule implementing the HOPE Act and the NIH Research Criteria necessitated that the OPTN update its standards of quality for HIV-positive organ transplants and coordinate related OPTN policies. On November 21, 2015, the OPTN published an open variance (an experimental policy that tests methods of improving organ allocation) providing standards for transplant hospitals conducting HOPE Act transplants.[7] The OPTN expanded the variance in 2019 to include all solid organs,[8] and extended the variance through January 2026, to provide for the gathering of data and subsequent evaluation of the outcomes of HOPE Act transplants.[9]

C. Review of Research Results

As stated above, the HOPE Act requires that the Secretary, in conjunction with the OPTN, periodically review the results of scientific research to determine whether the results warrant revision to the OPTN standards of quality with respect to organs from donors with HIV and the safety of transplanting an organ from a donor with a particular strain of HIV into a recipient with a different strain of HIV. 42 U.S.C. 274f–5(c)(1). This review allows the Secretary to determine if the safety and efficacy of HOPE Act transplants are comparable to non-HOPE Act transplants and, if warranted, to further determine whether such transplants should be conducted outside of a research setting.

1. OPTN Review and Recommendations

In 2018, the OPTN initiated a review of research results and data relevant to HOPE Act transplants, forming a working group for this purpose.[10] The OPTN's assessment as to whether revision is warranted for the OPTN standards of quality applicable to HOPE Act transplants was based primarily on (1) the review of studies demonstrating the safety and outcomes of organ transplantation in recipients with HIV and (2) a recognition that the removal of the general research and IRB requirements for HOPE Act transplants could expand access to organ transplantation for all patients regardless of their HIV status. In this context, safety is measured by accidental or inadvertent transmission of HIV in the performance of HOPE Act transplants. (Of note, there were no recorded accidental or inadvertent transmission events in the data reviewed by the OPTN.) Outcomes are determined primarily by transplant recipient or graft survival, compared to non-HOPE Act transplants or transplant recipients without HIV. Measures (*e.g.,* CD4+ T-cell counts, ART resistance, and detectable HIV viral loads) or variables such as opportunistic infections, HIV superinfection, malignancy, rejection or graft failure may also factor into comparative outcomes in the short and long term.

The OPTN used three primary sources of data to assess HOPE Act transplants, each of which contributed to the recommendation the OPTN provided to the Secretary: (1) the research results of two NIH-funded pilot studies evaluating HOPE Act kidney transplants and liver transplants, and the progress of two ongoing NIH-funded clinical trials evaluating HOPE Act kidney transplants and liver transplants, (2) the research results of an older clinical trial analyzing safety and efficacy of kidney transplants in a small cohort of transplant recipients with HIV, and (3) OPTN data on the outcomes of all HOPE Act transplants.

Pilot Studies

A multicenter pilot study funded by NIH was launched in 2016 to determine safety and efficacy of HOPE Act kidney transplants. The HOPE In Action Consortium of 14 transplant centers conducting HOPE Act kidney transplants which participated in the pilot study found that there were no major differences between HOPE Act transplants of a kidney from a donor with HIV to a recipient with HIV and non-HOPE Act kidney transplants from a donor without HIV to a recipient with HIV.[11] While donors with HIV were more likely to have co-infections, the study found that these were manageable in the larger clinical context. Rejection

[5] **Federal Register**. Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. 2015 Nov:80 FR 73785. *https://www.federalregister.gov/documents/2015/11/25/2015-30172/final-human-immunodeficiency-virus-hiv-organ-policy-equity-hope-act-safeguards-and-research-criteria.*

[6] *HIV.gov.* Opportunistic Infections: HIV Treatment Overview. *https://www.hiv.gov/hiv-basics/staying-in-hiv-care/other-related-health-issues/opportunistic-infections.* Accessed Apr 2024.

[7] Organ Procurement and Transplantation Network. Policy Notice: Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors. 2016 Sep 1: *https://optn.transplant.hrsa.gov/media/1872/dtac_policynotice_hope_201606.pdf.*

[8] Organ Procurement and Transplantation Network. Policy Notice: Modify HOPE Act Variance to Include Other Organs. 2019 Jun 10: *https://optn.transplant.hrsa.gov/media/3000/dtac_policynotice_201906.pdf.*

[9] Organ Procurement and Transplantation Network. Policy Notice: Extend HIV Organ Policy Equity (HOPE) Act Variance. 2021 Dec 6: *https://optn.transplant.hrsa.gov/media/t1sdej22/policy-notice_dtac_hope_variance.pdf.*

[10] Organ Procurement and Transplantation Network. Public Comment Proposal: Modify the HOPE Act Variance to Include Other Organs. 2019 Jan 22: *https://optn.transplant.hrsa.gov/media/2800/dtac_publiccomment_20190122.pdf.*

[11] Durand CM, Zhang W, Brown DM, Yu S, Desai N, Redd AD, Bagnasco SM, Naqvi FF, Seaman S, Doby BL, Ostrander D, Bowring MG, Eby Y, Fernandez RE, Friedman-Moraco R, Turgeon N, Stock P, Chin-Hong P, Mehta S, Stosor V, Small CB, Gupta G, Mehta SA, Wolfe CR, Husson J, Gilbert A, Cooper M, Adebiyi O, Agarwal A, Muller E, Quinn TC, Odim J, Huprikar S, Florman S, Massie AB, Tobian AAR, Segev DL; HOPE in Action Investigators. A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action. Am J Transplant. 2021 May;21(5):1754–1764.

was common for the study participants in the first year after transplant, occurring in 50 percent of recipients who received a kidney from a donor with HIV and 29 percent of recipients who received a kidney from a donor without HIV, but this result was not found to be statistically significant. The insignificance of the result is due, in part, to the relatively small sample size. In addition, the investigators indicated that this result could be due to chance. This finding is consistent with the earlier clinical trial of kidney transplantation in recipients with HIV, discussed in the next subsection of this preamble, which also found that rejection of such transplants is common. The pilot study investigators noted that despite rejection rates, 1-year renal function was excellent for both study populations. Limitations of the pilot study include study size (75 transplants), which investigators attributed to the lower number of HOPE Act transplants conducted than the projected potential. In general, the study authors concluded that there is a survival benefit of transplantation for kidneys from donors with HIV to recipients with HIV, and that the availability of HOPE Act kidney transplants has the potential to mitigate disparities for a vulnerable population that faces lower access to transplant and higher waitlist mortality. The investigators further concluded that the observed trend toward higher rejection, albeit not statistically significant, for transplanted organs from donors with HIV raises concerns that merited further investigation.

A separate pilot study funded by NIH and conducted by HOPE In Action Consortium participants compared HOPE Act transplants of a liver from a donor with HIV to a recipient with HIV and non-HOPE Act liver transplants from a donor without HIV to a recipient with HIV, and found that there were no differences in one-year graft survival, rejections, HIV breakthrough or severe adverse events. While the recipients of HOPE Act liver transplants presented with more opportunistic infections, infectious hospitalizations, and cancer, compared to non-HOPE Act liver transplants, the investigators determined that these findings warrant further investigation and perhaps consideration of additional donor and recipient infection and malignancy monitoring. In general, the investigators concluded that the transplant outcomes were more favorable compared to historical data on liver transplantation in recipients with HIV, who are known to experience higher rates of opportunistic infections and other complications. In addition, it was noted that co-infections are more common among both donors and recipients with HIV and confound the results. (Results of non-HOPE Act transplants have confirmed that recipients with both HIV and a co-infection have lower survival rates. Therefore, the presence of co-infections could independently impact survival and other variables measured by studies on HOPE Act transplants.) This pilot study was the first multicenter prospective study reporting results of U.S. transplants of livers from donors with HIV to recipients with HIV and comparing outcomes according to donor HIV status in order to assess attributable risk. The investigators recognized as a limitation that the pilot study was relatively small (45 transplants), and noted that the observed increases among HOPE Act liver transplant recipients in mortality, cytomegalovirus (CMV) viremia, infectious hospitalizations, and cancer. However, they note that these results should be considered in light of the relatively high rate of mortality for recipients awaiting liver transplant. For these patients, the benefit of undergoing a HOPE Act liver transplant may outweigh the risks of living with HIV and end stage liver disease.[12]

Ongoing Clinical Trials

Two NIH-funded studies on kidney and liver HOPE Act transplants are ongoing. The NIH-funded U01 HOPE Act kidney transplant clinical trial is designed to analyze rejection and long-term outcomes of kidney transplantation for recipients with HIV. The study will compare outcomes of 100 HOPE Act kidney transplant recipients to 100 kidney transplant recipients with HIV who received an HIV-negative organ at 15 transplant centers, adding to the cohort accrued from the pilot studies discussed in the immediately preceding section of this preamble.[13] Similarly, the U01 HOPE Act liver transplant clinical trial is designed to compare outcomes between HOPE Act transplants and non-HOPE Act transplants of livers from donors without HIV. The study has enrolled 40 individuals in each group over 3 years at 16 transplant centers.[14]

Both U01 clinical trials have reached their target enrollments and now in phases of final data analysis (kidney) and patient follow-up (liver). The final results are not yet published.

Other Research Results

Prior to the initiation of the pilot studies and clinical trials discussed previously, a clinical trial examined outcomes of 150 kidney transplants in recipients with HIV conducted between November 2003 and June 2009. The investigators found both recipient and graft survival rates were high with no important increases in complications associated with HIV.[15] As noted in the description of the findings of the HOPE Act kidney transplant pilot study described in the immediately preceding subsection of this preamble, the investigators observed what they described as ''unexpectedly higher'' rejection rates in the transplant recipients with HIV participating in the study, compared with kidney transplant recipients who are not living with HIV. This higher rejection rate was blunted in transplant recipients that received anti-T-cell antibody medication at the time of transplantation. Studies of non-HOPE Act transplants have confirmed that such immunosuppressive regimens can reduce the risk of rejection for kidney transplant recipients with HIV.[16]

OPTN Data—HOPE Act Transplant Outcomes

Data from HOPE Act transplants is compiled by the OPTN on a quarterly basis, including waitlist registrations and counts of HOPE Act transplants, and is routinely reviewed. Prior to issuing its recommendation to the Secretary, the OPTN reviewed data on over 300 patients included in the HOPE

[12] Durand CM, Florman S, Motter JD, Brown D, Ostrander D, Yu S, Liang T, Werbel WA, Cameron A, Ottmann S, Hamilton JP, Redd AD, Bowring MG, Eby Y, Fernandez RE, Doby B, Labo N, Whitby D, Miley W, Friedman-Moraco R, Turgeon N, Price JC, Chin-Hong P, Stock P, Stosor V, Kirchner VA, Pruett T, Wojciechowski D, Elias N, Wolfe C, Quinn TC, Odim J, Morsheimer M, Mehta SA, Rana MM, Huprikar S, Massie A, Tobian AAR, Segev DL; HOPE in Action Investigators. HOPE in action: A prospective multicenter pilot study of liver transplantation from donors with HIV to recipients with HIV. Am J Transplant. 2022 Mar;22(3):853–864.

[13] National Institutes of Health RePORT. Kidney Transplantation from Donors with HIV: Impact on Rejection and Long-term Outcomes. Project No. 5U01AI177211–02. Accessed 21 May 2024. *https://reporter.nih.gov/search/kcWJ0GeT8kigjO2_LU8R2g/project-details/10848468.*

[14] National Institutes of Health RePORT. Hope In Action: A Clinical Trial of HIV-to-HIV Liver Transplantation. Project No. 5U01AI138897–05. Accessed 21 May 2024. *https://reporter.nih.gov/project-details/10459319.*

[15] Stock PG, Barin B, Murphy B, Hanto D, Diego JM, Light J, Davis C, Blumberg E, Simon D, Subramanian A, Millis JM, Lyon GM, Brayman K, Slakey D, Shapiro R, Melancon J, Jacobson JM, Stosor V, Olson JL, Stablein DM, Roland ME. Outcomes of kidney transplantation in HIV-infected recipients. N Engl J Med. 2010 Nov 18;363(21):2004–14.

[16] Locke JE, James NT, Mannon RB, Mehta SG, Pappas PG, Baddley JW, Desai NM, Montgomery RA, Segev DL. Immunosuppression Regimen and the Risk of Acute Rejection in HIV-Infected Kidney Transplant Recipients. Transplantation. 2014 Feb 27;97(4):p 446–450.

Act research variance for which no case was halted, paused, or substantially amended to address safety concerns.

OPTN Recommendations

Based on the assessment of the above-described research results and data, in 2021 the OPTN recommended to the Secretary that the research and IRB requirements of the HOPE Act be removed for all organs.[17] The OPTN specifically noted that in its review of the data safety monitoring review board (DSMB) reports from five years of HOPE Act transplants, with over 300 persons with HIV receiving HOPE Act transplants, no DSMB identified patient safety concerns in HOPE Act research. Further, there have been no reports 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. The OPTN noted that it was the opinion of the OPTN Safety Review Group that the research and IRB requirements for HOPE Act transplants present a barrier to fully realizing the potential of organ transplantation from donors with HIV to recipients with HIV, as the research and IRB requirements limit access to such transplants.[18] [19]

2. Additional Research Results Published Subsequent to the OPTN Assessment

Following the OPTN's review of research results and data relevant to HOPE Act transplants and its recommendation to the Secretary, additional research has since been published providing more evidence for the safety of organ transplantation from donors with HIV to recipients with HIV. In general, safety and outcomes of kidney and liver HOPE Act transplants is well established with over 468 HOPE Act kidney and liver transplants conducted to date.

One prospective study published in 2022, examined 92 HOPE Act donors contributing 177 organs, which included 131 kidneys and 46 livers, to understand the characteristics of donors with HIV in terms of clinical, immunologic, and virologic profiles to ensure the safety of transplantation. Of these donors, 58 were donors with HIV and 34 were donors without HIV. For those donors with known HIV infection, 90 percent received ART treatment. The study concluded that although drug resistant mutations (DRMs) were common, DRMs that could compromise the effectiveness of certain ART were rare, reassuring the safety of using donor organs with HIV in recipients with HIV. Further, the study also found that there were no major differences comorbidities between recipient groups that received an organ from a donor with HIV compared to those that received an organ from a donor without HIV.[20]

In a March 2024 analysis of the impact of the HOPE Act on access to kidney transplantation for recipients with HIV, the authors found 70 percent of HOPE Act recipients received a kidney transplant during the 4.5 year study period versus 43 percent of non-HOPE Act transplant candidates at the same center.[21] Furthermore, those who received transplants in HOPE Act trials had shorter estimated wait times (median 10.3 months versus 60.8 months), and after adjusting for relevant allocation factors including time on dialysis, kidney transplantation was 3.3-fold higher for those who received an organ from a donor with HIV.[22] These findings suggest that the availability of kidneys from donors with HIV increases access to transplantation among people with HIV. Given that people with HIV who are living with ESRD have higher mortality than people with ESRD who are not also living with HIV,[23] in HHS's view, this data illustrates the benefit of HOPE Act kidneys transplants for this vulnerable population.

In addition to providing important evidence for the survival benefit of organ transplantation for recipients with HIV, the HOPE in Action Consortium has also published on the positive outcomes of living HOPE Act kidney donors. In a case series of three transplants, investigators reported that two of the three donors developed adverse events, but findings suggested these were medically managed and that HIV RNA copies and CD4+ T-cell counts were stable at two to four years post-transplant.[24]

There is significantly less data on non-kidney and non-liver HOPE Act transplants. Since 2019, when the OPTN's HOPE Act policy was expanded to include all solid organs, only three heart transplant programs have received approval to perform HOPE Act transplants. To date, just one heart transplant has been conducted (dual organ: heart-kidney).[25] [26] No HOPE Act transplants have been recorded among recipients in need of organs such as a lung, pancreas, islet, or intestine. The lack of data makes it difficult to assess the safety and outcomes of HOPE Act transplants other than kidney and liver HOPE Act transplants.

3. HHS Advisory Committee on Blood and Tissue Safety and Availability Recommendations

Following the OPTN recommendation to the Secretary in 2021, the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) formed a Working Group to evaluate the recommendation from the OPTN. After analyzing the OPTN recommendation, and receiving presentations on data on HOPE Act kidney and liver transplants, and relevant research results on heart transplants and lung transplants in recipients with HIV, the ACBTSA HOPE Act working group recommended to the full committee that the Secretary

[17] Cooper M. ''OPTN Letter to Secretary Becerra on the HOPE Act.'' 2021 Oct 29. *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf.*

[18] McCauley J. ''Fifty Sixth ACBTSA Meeting, Written Public Comment—November 17, 2022 Meeting.'' 2022 Nov 8. *https://optn.transplant.hrsa.gov/media/hwgncda2/optn-executive-committee_acbtsa-letter.pdf.*

[19] Chandran S, Stock PG, Roll GR. Expanding Access to Organ Transplant for People Living With HIV: Can Policy Catch Up to Outcomes Data? Transplantation. 2024 Apr 1;108(4):874–883.

[20] Werbel WA, Brown DM, Kusemiju OT, Doby BL, Seaman SM, Redd AD, Eby Y, Fernandez RE, Desai NM, Miller J, Bismut GA, Kirby CS, Schmidt HA, Clarke WA, Seisa M, Petropoulos CJ, Quinn TC, Florman SS, Huprikar S, Rana MM, Friedman-Moraco RJ, Mehta AK, Stock PG, Price JC, Stosor V, Mehta SG, Gilbert AJ, Elias N, Morris MI, Mehta SA, Small CB, Haidar G, Malinis M, Husson JS, Pereira MR, Gupta G, Hand J, Kirchner VA, Agarwal A, Aslam S, Blumberg EA, Wolfe CR, Myer K, Wood RP, Neidlinger N, Strell S, Shuck M, Wilkins H, Wadsworth M, Motter JD, Odim J, Segev DL, Durand CM, Tobian AAR; HOPE in Action Investigators. National Landscape of Human Immunodeficiency Virus-Positive Deceased Organ Donors in the United States. Clin Infect Dis. 2022 Jun 10;74(11):2010–2019.

[21] Motter JD, Hussain S, Brown DM, Florman S, Rana MM, Friedman-Moraco R, Gilbert AJ, Stock P, Mehta S, Mehta SA, Stosor V, Elias N, Pereira MR, Haidar G, Malinis M, Morris MI, Hand J, Aslam S, Schaenman JM, Baddley J, Small CB, Wojciechowski D, Santos CAQ, Blumberg EA, Odim J, Apewokin SK, Giorgakis E, Bowring MG, Werbel WA, Desai NM, Tobian AAR, Segev DL, Massie AB, Durand CM; HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

[22] Motter JD, et al, on behalf of 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. 2024 Mar 1;108(3):759–767.

[23] *Ibid.*

[24] Durand CM, et al, on behalf of the HOPE in Action Investigators. Living Kidney Donors with HIV: Experience and Outcomes from a Case Series by the HOPE in Action Consortium. The Lancet Regional Health Americas. 2023 Jul;24:100553.

[25] Montefiore News Releases. World's First HIV-Positive to HIV-Positive Heart Transplant Performed at Montefiore Health System. 2022 Jul 22. *https://www.montefiore.org/body.cfm?id=1738&action=detail&ref=2194*

[26] Hemmige V, Saeed O, Puius YA, Azzi Y, Colovai A, Borgi J, Goldstein DJ, Rahmanian M, Carlese A, Jorde UP, Patel S. HIV D+/R+ heart/kidney transplantation: First case report. J Heart Lung Transplant. 2023 Mar;42(3):406–408.

eliminate research and IRB requirements for all HOPE Act transplants. However, the working group expressed concern about the elimination of research and IRB requirements for non-kidney and non-liver HOPE Act transplants,[27] and whether there was sufficient data collected on other organs to justify a full adoption the OPTN's recommendation.

The ACBTSA subsequently recommended that the Secretary act to lift the statutory research and IRB requirements for all HOPE Act transplants and at the same time recommended that the Secretary direct the OPTN to adopt, for HOPE Act transplants of organs other than kidneys and livers, organ-specific policies imposing additional requirements for the conduct of these transplants, including collecting safety and outcomes data for transplant candidates and recipients of such transplants through an IRB-approved research protocol.

These recommendations were later approved by the HHS Blood, Organ, and Tissue Senior Executive Council (BOTSEC), an advisory forum for senior leadership from HHS entities involved in blood, organ, and tissue safety and availability.

4. HHS Secretary: Review

Upon review of the OPTN, ACBTSA and BOTSEC recommendations, and in consideration of the results of relevant scientific research, the Secretary believes that the research and IRB requirements for kidney and liver HOPE Act transplants are no longer warranted.

The Secretary has been informed by the research results described in this preamble from pilot studies, clinical trials, and case reports, as well as OPTN outcomes data on all HOPE Act transplants and additional data. Studies of kidney and liver HOPE Act transplants have demonstrated survival benefit for transplant recipients with HIV, compared to non-HOPE Act transplants, with few adverse consequences.[28] [29] [30] Additionally, the OPTN's letter to the Secretary noted that in five years of HOPE Act transplants with over 300 HOPE Act transplant recipients with HIV, no patient safety concerns were identified, and no HOPE Act research has been halted, paused, or substantially amended to address recipient safety concerns.[31]

The outcomes of HOPE Act transplants are considered in light of the limitations of organ transplantation generally: that too few organs are available for the thousands of patients awaiting transplants. The pretransplant mortality rate for adults awaiting a kidney transplant varies substantially across the country. The average is 5.4 deaths per 100 person years, but it is reported to be as high as 7.5 deaths per 100 person years as of the most recent OPTN/SRTR Annual Data Report.[32] This results in most transplant candidates waiting years for a kidney transplant, often requiring dialysis or other interventions.

It is well established that pretransplant kidney mortality rates among candidates with HIV are higher than those without HIV. In one study analyzing survival benefit of HIV-positive kidney transplantation (*i.e.,* non-HOPE Act transplants), mortality rates among transplant candidates with HIV after one year were 8.7 deaths per 100 person years compared to just 3.1 deaths per 100 person years among those that received a kidney transplant.[33] Therefore, it is hypothesized that reduction in waitlist times may indeed result in lower mortality for transplant candidates with HIV and end-stage diseases.

Research has demonstrated that recipients with HIV may reduce the time on the kidney waitlist significantly if they are willing to accept a HOPE Act transplant. As previously mentioned, one 2023 study found that median wait time for a HOPE Act transplant was 10.8 months compared to 60.8 months—a 3.3-fold higher rate of kidney transplant compared to non-HOPE Act transplants.[34]

Significant progress has been made in the reduction of pretransplant mortality for liver transplant candidates over the past decade. Rates have declined from a high of 17.9 deaths per 100 person years in 2014 to 12.3 deaths per 100 person years in 2022.[35] Like kidney transplant, research has also demonstrated the survival benefit of organ transplantation for those with HIV and end-stage liver disease when compared to transplant candidates without HIV.[36]

It is also hypothesized that the expansion of kidney and liver HOPE Act transplantation will also help to reduce stigma and health disparities associated with HIV. Stigma and physician reluctance to counsel potential transplant candidates with HIV on the benefits of organ transplantation may contribute to the lower than projected counts of HOPE Act transplants to date.[37]

The Secretary also believes that the current research and IRB requirements should be maintained for HOPE Act transplants of all other organs, in light of the lack of data on outcomes for HOPE Act organ transplants other than kidney or liver transplants. At the time the ACBTSA developed its recommendations, no HOPE Act transplants outside of kidneys, livers, and one dual heart-kidney transplant had been performed, and data on heart, lung, pancreas, islet, intestine, or other organ transplants from donors with HIV to recipients with HIV that were conducted outside the U.S. is limited.

The HOPE Act requires that, for the statutory research and IRB requirements to be lifted for HOPE Act transplants, the Secretary must determine that participation in such clinical research, as a requirement for these transplants, is no longer warranted. 42 U.S.C. 274 (b)(3)(B)(ii). In the absence of research results and robust outcomes data

[27] HHS Advisory Committee on Blood and Tissue Safety and Availability. 2022. Fifty-Sixth ACBTSA Meeting November 17, 2022—Meeting Summary. *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meeting-summary/2022-11-17/index.html.*

[28] Durand CM, et al; HOPE in Action Investigators. A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action. Am J Transplant. 2021 May;21(5):1754–1764.

[29] Durand CM, et al; HOPE in Action Investigators. HOPE in action: A prospective multicenter pilot study of liver transplantation from donors with HIV to recipients with HIV. Am J Transplant. 2022 Mar;22(3):853–864.

[30] Motter JD, et al; HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

[31] Cooper M. ''OPTN Letter to Secretary Becerra on the HOPE Act.'' 2021 Oct 29. *https://optn.transplant.hrsa.gov/media/ueyjdfnd/hope-act-letter.pdf.*

[32] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2022. ''Annual Data Report: Kidney.'' Accessed May 2024. *https://srtr.transplant.hrsa.gov/annual_reports/2022/Kidney.aspx.*

[33] Locke JE, Gustafson S, Mehta S, Reed RD, Shelton B, MacLennan PA, Durand C, Snyder J, Salkowski N, Massie A, Sawinski D, Segev DL. Survival Benefit of Kidney Transplantation in HIV-infected Patients. Ann Surg. 2017 Mar;265(3):604–608.

[34] Motter JD, et al; HOPE in Action Investigators. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. Transplantation. 2024 Mar 1;108(3):759–767.

[35] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2022. ''Annual Data Report: Liver.'' Accessed May 2024. *https://srtr.transplant.hrsa.gov/annual_reports/2022/Liver.aspx.*

[36] Ragni MV, Eghtesad B, Schlesinger KW, Dvorchik I, Fung JJ. Pretransplant survival is shorter in HIV-positive than HIV-negative subjects with end-stage liver disease. Liver Transpl. 2005 Nov;11(11):1425–30.

[37] Klitenic SB, Levan ML, Van Pilsum Rasmussen SE, Durand CM. Science Over Stigma: Lessons and Future Direction of HIV-to-HIV Transplantation. Curr Transplant Rep. 2021;8(4):314–323.

relevant to HOPE Act transplants of organs other than kidneys and livers, the Secretary does not have sufficient information about transplants of organs other than kidneys and livers on which to base the statutorily required determination.

The Secretary acknowledges that the OPTN has argued that any research and IRB requirements serve as a barrier to access for HOPE Act transplant candidates and may perpetuate inequities in HOPE Act transplant programs.[38] We believe, however, that the proposed rule balances the need to ensure the safety of HOPE Act transplants while removing research and IRB requirements for HOPE Act kidney and liver transplants in transplant programs that are well established and have demonstrated both efficacy and safety.

D. Diversity, Equity, Inclusion: Effects on Individuals in Need of Transplant

Currently, only a limited number of centers can perform HOPE Act transplants, because there are specific requirements stipulated by the NIH Research Criteria for such transplant centers. These requirements include expertise in HIV infection management, minimum organ-specific transplant team experience of five transplants of organs from donors without HIV to recipients with HIV over four years and an independent advocate for both recipients with HIV and prospective living donors with HIV. The requirements for centers conducting HOPE Act transplants have been subject to critique and have been viewed as a barrier to participation in HOPE Act transplant programs, which may impact equity and access to organ transplantation throughout the United States.[39] By eliminating the requirement that HOPE Act kidney and liver transplants are conducted in the research context, it is anticipated that a larger number of transplant centers will be able to conduct such transplants. This proposal will enable more transplant centers to transplant kidneys and livers donated by both living and deceased donors with HIV, in recipients with HIV, thereby expanding opportunities for people with HIV and end-stage diseases.

Other factors, such as systemic racism, perpetuate long-standing inequalities and inequities in health care access including organ transplantation. People who identify as Black or African American are four times more likely to develop ESRD compared to non-Hispanic White people but are less likely to receive a kidney transplant.[40] [41] These outcomes are not explained by individual characteristics alone, suggesting that other factors, such as lower socioeconomic status and poor clinical communication, contribute to this inequity.[42] [43]

Separate from organ transplantation, HIV disproportionately affects people of some racial and ethnic groups in the United States, such as Black or African American and Hispanic or Latino populations. Prevalence rates suggest these communities have higher rates of HIV compared to White populations. For example, according to the Centers for Disease Control and Prevention's (CDC) HIV Surveillance Supplemental Report, 2023, people who identified as Black or African American represented 12.4 percent of the population but 40.2 percent of those with diagnosed HIV in 2021.[44] In addition, people identified as Hispanic or Latino represent 17.6 percent of the population but make up 23.8 percent of people with diagnosed HIV.[45] Incidence rates also confirm that new infections disproportionately affect Black or African Americans (40 percent of new infections), and Hispanic or Latinos (29 percent of new infections), suggesting that prevention efforts are not adequately reaching these populations.[46] Higher prevalence and incidence rates among communities over-represented in the HIV epidemic suggest that these communities would also benefit from expanded access to HOPE Act transplants. In fact, in one 2019 study of HOPE Act deceased-donor characteristics, investigators found a higher proportion of people who identify as Black or African American (72 percent) among HOPE Act kidney transplant recipients than the percent of Black or African Americans in the general population. Among recipient characteristics of HOPE Act liver transplant recipients in the same study, 23 percent identified as Black or African American.[47]

In addition to racial and ethnic diversity, gay, bisexual, and other men who have sex with men (MSM) are the most affected group of people with HIV, accounting for 66 percent of new infections in 2021 even though they only compose 2 percent of the population.[48] [49] Lastly, people who identify as transgender represent 2 percent of all new HIV diagnoses, exceeding the proportion of people who identify as transgender in the general population.[50]

In light of all of these considerations, HHS expects that this proposed rule, if finalized, will assist in improving access to kidney and liver transplants for recipients with HIV. This anticipated positive result is consistent with the Department's commitment to diversity, equity, and inclusion.

Further, this proposed rule to remove research and IRB requirements for kidney and liver HOPE Act transplants would, if finalized, expand access to organ transplantation for all patients, regardless of their HIV status. When eligible for transplant, a person with HIV is added to the waiting list. That patient may elect to receive an organ from a donor with HIV, as a HOPE Act transplant, should it become available, or may choose to wait for an organ from a donor who did not have HIV. If the patient with HIV chooses the HOPE Act

[38] McCauley J. ''Fifty Sixth ACBTSA Meeting, Written Public Comment—November 17, 2022 Meeting.'' 2022 Nov 8. *https://optn.transplant.hrsa.gov/media/hwgncda2/optn-executive-committee_acbtsa-letter.pdf.*

[39] Bowring, M.G., Ruck, J.M., Bryski, M.G., Werbel, W., Tobian, A.A.R., Massie, A.B., Segev, D.L., & Durand, C.M. (2023). Impact of expanding HOPE Act experience criteria on program eligibility for transplantation from donors with human immunodeficiency virus to recipients with human immunodeficiency virus. American Journal of Transplantation, 23(6), 860–864.

[40] National Institute of Diabetes and Digestive and Kidney Diseases. n.d. Kidney Disease Statistics for the United States. Accessed February 2024. *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.*

[41] U.S. Department of Health and Human Services. Office of Minority Health: Organ Donation and African Americans. *https://minorityhealth.hhs.gov/organ-donation-and-african-americans.* Accessed 2/27/2024.

[42] El-Khoury B, Yang TC. Reviewing Racial Disparities in Living Donor Kidney Transplantation: a Socioecological Approach. J Racial Ethn Health Disparities. 2023 Mar 29:1–10.

[43] Siminoff LA, Burant CJ, Ibrahim SA. Racial disparities in preferences and perceptions regarding organ donation. J Gen Intern Med. 2006 Sep;21(9):995–1000.

[44] Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2017–2021. HIV Surveillance Supplemental Report, 2023; 28 (No.3). *https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.* Published May 2023.

[45] *Ibid.*

[46] Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2017–2021. HIV Surveillance Supplemental Report, 2023; 28 (No.3). *https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.* Published May 2023.

[47] Wilk AR, Hunter RA, McBride MA, Klassen DK. National landscape of HIV+ to HIV+ kidney and liver transplantation in the United States. American Journal of Transplantation 2019;19(9):2594–2605.

[48] Centers for Disease Control and Prevention. Surveillance Supplemental Report, 2023, 2003 May;28(No.3). *https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.*

[49] Purcell DW, Johnson CH, Lansky A, et al. Estimating the population size of men who have sex with men in the United States to obtain HIV and syphilis rates. Open AIDS J 2012; 6:98–107.

[50] Centers for Disease Control and Prevention. HIV Surveillance Report, 2021; vol. 34. *https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.* Published May 2023.

transplant, this will allow another patient on the waiting list to receive the next available organ from a donor who does not have HIV, which would reduce the time spent waiting for a transplant. Of note, patients who do not have HIV will not be offered an organ from a donor who has HIV, as such transplants are not allowed under Federal law.

As of February 16, 2024, more than 103,000 men, women, and children were on the national organ transplant waiting list.[51] Every 10 minutes another person is added to the waiting list, and nearly 20 people die every day while waiting for a transplant.[52] The current approach to acquiring organs for transplantation relies on the altruism of donors and their families.

According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), more than 1 in 7 adults in the U.S. are affected by kidney disease.[53] Of those, more than 800,000 Americans are living with end-stage renal disease (ESRD), a condition that often requires renal dialysis or kidney transplant.[54] Kidney transplants in 2023 set a new record, offering 27,332 ESRD patients and their families a life-changing organ.[55] Despite upward trends in the number of kidney transplants conducted year over year, tens of thousands of Americans remain on the waiting list, which currently exceeds 88,700 candidates.[56] The 2022 OPTN/U.S. Scientific Registry of Transplant Recipients (SRTR) Annual Data Report indicated that over the course of a year more than 4,400 adults died while waiting for a kidney transplant, and an additional 4,500 persons were removed from the waiting list because they became too sick to receive a transplant.[57] Furthermore, at least 562,000 Americans endure renal dialysis each year, often while awaiting a kidney transplant.[58]

In addition, thousands of Americans suffer from conditions requiring liver transplant. In 2023, more than 10,660 liver transplants were carried out with organs from both living and deceased donors, setting an all-time record.[59] As of February 16, 2024, 9,882 candidates remain on the waiting list, but additional registrations are expected throughout the year.[60] In 2021, more than 1,100 liver patients died while awaiting transplant, according to the OPTN/SRTR Annual Data Report.[61]

As such, HHS believes regulatory changes designed to increase the number of organs available for donation, such as those proposed in this rule, could mitigate these outcomes. HHS is committed to reducing the number of persons on the organ transplant waiting list by increasing the number of organs made available for transplantation.

E. Implementation Considerations

1. NIH Research Criteria

The HOPE Act provides the Secretary with the discretion to determine what research criteria should apply to HOPE Act transplants. 42 U.S.C. 274f–5(a). If this proposed rule is finalized, HHS anticipates that NIH will, in consultation with HRSA and the OPTN, and including the input of other relevant Federal stakeholders, revise and publish updated Research Criteria in the **Federal Register** for public comment later this year. The Research Criteria, as originally drafted, include a strong focus on HOPE Act kidney and liver transplants, as these are the most common types of HOPE Act transplants. As the current Research Criteria will no longer be applicable to HOPE Act kidney and liver transplants once the Secretary's determination is implemented, much of the current criteria will no longer be relevant.

Further, HHS recognizes it will be appropriate to update the NIH Research Criteria to reflect advances in research in the time since HOPE Act transplants began. The research criteria should reflect the current needs of various entities involved in HOPE Act transplants in consideration of input from transplant centers, transplant surgeons, OPOs, HIV clinicians, donors, recipients, HIV advocates, the OPTN, and individuals affected by the HOPE Act.

2. Secretarial Direction To Revise OPTN Policies

Should this proposed rule be finalized, the Secretary must direct the OPTN to update its policies to clarify that HOPE Act kidney and liver transplants may be conducted in a way consistent with the statutory requirements at 42 U.S.C. 274, and that ensures the revisions to the policies will not reduce the safety of organ transplantation. 42 U.S.C. 274f–5(c)(2); 42 CFR 121.6(b)(3). Through this NPRM, HHS specifically seeks public comment on the nature and content of the Secretary's direction to the OPTN, including the level of specificity in the direction and the extent of the OPTN's discretion in developing the revised policies; what factors should be considered in assessing whether the revised policies are consistent with 42 U.S.C. 274; and what factors should be considered in assessing whether the revisions to the OPTN policies will not reduce the safety of organ transplantation. HHS further welcomes comment on any other aspects relating to the Secretary's direction to the OPTN to revise its standards of quality as required by the HOPE Act.

HHS expects that the OPTN would solicit public comment on a proposed revision to relevant OPTN policies, and update the OPTN policies containing standards of quality with respect to kidneys and livers from donors with HIV, within 15 months from the publication of a final rule.

F. Secretarial Determination

The Secretary has reviewed the recommendations of the OPTN, the ACBTSA, and the BOTSEC on implementation of the HOPE Act, and the results of research on HOPE Act transplants conducted to date as well as results of other relevant research on organ transplants in recipients with HIV. Pursuant to his authority under the HOPE Act, 42 U.S.C. 274(b)(3)(B)(ii), and consistent with the implementing regulations at 42 CFR 121.6, the Secretary proposes to determine that participation in clinical research, and

[51] Organ Procurement and Transplantation Network. 2024. *Dashboard and metrics.* Accessed February 2024. *https://insights.unos.org/OPTN-metrics/.*

[52] Health Resources and Services Administration. *Organ Donation Statistics.* Accessed February 2024. *https://www.organdonor.gov/learn/organ-donation-statistics.*

[53] National Institute of Diabetes and Digestive and Kidney Diseases. n.d. Kidney Disease Statistics for the United States. Accessed February 2024. *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.*

[54] National Institute of Diabetes and Digestive and Kidney Diseases. n.d. Kidney Disease Statistics for the United States. Accessed Feb 2024. *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.*

[55] *Ibid.*

[56] Organ Procurement and Transplantation Network. Dashboard and metrics. *https://insights.unos.org/OPTN-metrics/.* Accessed Feb 2024.

[57] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2021. ''Annual Data Report.'' Accessed Feb 2024. *https://srtr.transplant.hrsa.gov/annual_reports/2021_ADR_Preview.aspx.*

[58] National Institute of Diabetes and Digestive and Kidney Diseases. n.d. Kidney Disease Statistics for the United States. Accessed Feb 2024. *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.*

[59] United Network for Organ Sharing (UNOS). February 14, 2024. A decade of record increases in liver transplant. Accessed Feb 2024. *https://unos.org/news/in-focus/a-decade-of-record-increases-in-liver-transplant/.*

[60] Organ Procurement and Transplantation Network. Dashboard and metrics. *https://insights.unos.org/OPTN-metrics/.* Accessed Feb 2024.

[61] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2021. ''Annual Data Report.'' Accessed February 2024. *https://srtr.transplant.hrsa.gov/annual_reports/2021_ADR_Preview.aspx.*

therefore adherence to research and IRB requirements, as a requirement for transplants of kidneys and livers from persons with HIV, is no longer warranted. Through this rulemaking, the Secretary proposes to lift the statutory research and IRB requirements for such transplants.

Through this NPRM, HHS specifically seeks public comment on the Secretary's proposed determination that participation in clinical research, and application of the statutory research and IRB requirements, as a requirement for transplants of kidneys and livers from persons with HIV, is no longer warranted.

III. Discussion of the Proposed Rule

A. Removal of Research and IRB Requirements for HOPE Act Kidney and Liver Transplants

Consistent with the Secretary's proposed determination under the HOPE Act, this proposed rule, if finalized, will revise § 121.6 of the HHS regulations governing the OPTN to reflect the removal of the statutory research and IRB requirements for kidney and liver HOPE Act transplants.

HHS proposes to revise § 121.6(b)(1)(ii)(B) to reflect the Secretary's proposed determination that participation in clinical research is no longer warranted for the following categories of transplants:

(1) Transplant of a donor kidney with HIV; and

(2) Transplant of a donor liver with HIV.

In implementation, this proposal, if approved, would mean that HOPE Act kidney and liver transplants will no longer be conducted as research, and instead will be conducted in accordance with newly adopted OPTN policies regarding kidneys and livers from donors with HIV.

B. Revised Terminology: Persons With HIV

HHS is aware that previous language used in enacting and implementing the HOPE Act contained vocabulary and phrases that some people find stigmatizing—namely, references to ''infected with HIV'' when the regulatory language encompasses both living and deceased donors with HIV, or recipients with HIV. For the references to both living and deceased donors with HIV, HHS proposes to revise all current references in § 121.6(b) from ''individuals infected with human immunodeficiency virus (HIV)'' and ''individuals infected with HIV'' to ''donors with HIV'' or, when discussing organs donated, ''donor organs with HIV.'' Further, HHS proposes to revise the current reference in § 121.6(b)(1)(i) describing the allowable recipients of HOPE Act transplants from individuals who are ''infected with HIV before receiving such organ(s)'' to instead refer to individuals who are ''living with HIV before receiving such organ(s).'' This is consistent with the Centers for Disease Control and Prevention's (CDC) Stigma Language Guide.[62]

HHS is proposing these new regulatory references to ''donors with HIV'' and ''living with HIV'' with the intent to be respectful, and not to change the group of people referenced in the current § 121.6.

V. Explanation of the 30-Day Public Comment Period

HHS is publishing this proposed rule with a 30-day public comment period, as multiple opportunities for public input on the matters addressed through this rulemaking already have been provided. HHS has been collecting public commentary on the HOPE Act since the OPTN provided its HOPE Act recommendations to Secretary Becerra in October 2021. ACBTSA heard a summary of the OPTN's consideration of the HOPE Act soon after its December 1, 2021 public meeting. Following this presentation, ACBTSA formed a working group to develop a recommendation regarding the HOPE Act. During the ACBTSA's November 17, 2022 public meeting, ACBTSA received written public comment on its proposed recommendations to the Secretary regarding removing the research and IRB requirements for kidney and liver HOPE Act transplantations.[63]

HHS has actively engaged transplant surgeons, researchers, advocates, donors, and recipients involved in organ transplantation in the course of drafting a recommendation to the Secretary. The Department has reviewed dozens of comments received in response to discussions held by the ACBTSA, the BOTSEC and the Presidential Advisory Council on HIV/AIDS (PACHA).[64] [65] The Department understands that there is widespread support for the proposed recommendation including the endorsement of at least 35 non-governmental organizations involved in HIV advocacy, organizations representing entities involved in organ transplantation, associations representing transplant surgeons, nephrologists, HIV clinicians, epidemiologists, and many more individuals.

Given the multiple committees and policy mechanisms employed for discussion of potential changes to requirements for HOPE Act transplants, previous efforts to gather public commentary and the considerable public health impact this proposed policy may have on those in need of organ transplantation, HHS believes the 30-day public comment period is sufficient and most expedient.

VI. Paperwork Reduction Act of 1995

This proposed rule, if finalized, would not impose any additional information collection burden under the Paperwork Reduction Act and does not contain any information collection requirements beyond those already imposed by current regulations, which have been approved by the Office of Management and Budget. The current data collection requirements in the OPTN final rule approved by the OMB under the Paperwork Reduction Act of 1995 are assigned control numbers OMB No. 0915–0157 (for organ donors, candidates, and recipients) and OMB No. 0915–0184 (for OPTN membership application data).

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 section 3(f)(1) (as amended by Executive Order 14094) if they have an annual effect on the economy of $200 million or more (adjusted every 3 years

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[62] Centers for Disease Control and Prevention. Let's Stop HIV Together: Stigma Language Guide. *https://www.cdc.gov/stophivtogether/hiv-stigma/ways-to-stop.html.* Accessed 2/23/2024.

[63] HHS Advisory Committee on Blood and Tissue Safety and Availability. 2022. Fifty-Sixth ACBTSA Meeting November 17, 2022—Meeting Summary.

[64] 79th Presidential Advisory Council on HIV/AIDS (PACHA) Full Council Meeting |12.06.23 | Part 4. Uploaded by U.S. Department of Health and Human Services. 2023 Dec 14. *https://www.youtube.com/watch?v=oHM3ygWpMek.*

[65] HHS Presidential Advisory Council on HIV/AIDS (PACHA). Seventy-Ninth PACHA Meeting December 6, 2023—Meeting Summary. 2023 Dec 6. *https://files.hiv.gov/s3fs-public/2024-03/PACHA-Dec-2023-meeting-summary-final.pdf.*

by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities. This analysis indicates that this proposed rule is a significant regulatory action under Executive Order 12866 section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the impacts are small relative to the number of organ transplants performed annually, and because the costs are small relative to the average payroll of firms in the smallest enterprise size category, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (UMRA) generally requires that each agency conduct a cost-benefit analysis, identify and consider a reasonable number of regulatory alternatives, and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule before promulgating any proposed or final rule that includes a Federal mandate that may result in expenditures of more than $100 million (adjusted for inflation) in at least one year by State, local, and Tribal governments, or by the private sector. Each agency must also seek input from State, local, and Tribal governments.[66] The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is $183 million, reported in 2023 dollars. This proposed rule, if finalized, would not result in an unfunded mandate in any year that meets or exceeds this amount.

This proposed rule would, if finalized, remove the current research and institutional review board (IRB) requirements for transplants of human immunodeficiency virus (HIV)-positive kidneys and livers. This would result in impacts related to changes in the number of kidney and liver transplants performed annually. We monetize benefits associated with increases in life expectancy for organ transplant recipients and, for kidney transplant recipients, benefits associated with improved quality of life and time savings from fewer kidney dialysis visits. We monetize costs from medical expenditures associated with organ transplantation; for kidney transplants, we report impacts that are net of medical expenditures associated with kidney dialysis. We also monetize costs associated with organ transplant centers reading and understanding the rule, reviewing policies and procedures, and training staff. We report the shift in expenditures associated with kidney dialysis to expenditures associated with kidney transplantation separately as transfers. We estimate that the annualized benefits over a 10-year time horizon covering 2025 through 2034 would range from $561 million to $1.26 billion at a 2 percent discount rate, with a primary estimate of $900 million. The annualized costs would range from $134 million to $174 million, with a primary estimate of $154 million. The annualized transfers would range from $24 million to $39 million, with a primary estimate of $31 million.

TABLE 1—SUMMARY OF IMPACTS OF THE PROPOSED RULE

[Millions of constant 2023 dollars

Category	Primary estimate	Low estimate	High estimate	Dollar year or unit	Discount rate (%)	Time horizon	Notes
BENEFITS:							
Annualized monetized benefits.	$900	$561	$1,261	2023	2	2025–2034	Increased life expectancy for organ transplant recipients; improved quality of life for kidney transplant recipients; time savings from fewer kidney dialysis visits.
Annualized quantified, but non-monetized, benefits.	147	129	166	People affected	2	2025–2034	Improved quality of life for liver transplant recipients.
Unquantified benefits.						2025–2034	Time savings for caregivers; cost savings related to removing the research and institutional review board requirements.
COSTS:							
Annualized monetized costs.	$154	$134	$174	2023	2	2025–2034	Net costs associated with organ transplants; costs associated with organ transplant centers reading and understanding the rule, reviewing policies and procedures, and training staff.
TRANSFERS:							
Annualized monetized transfers.	$31	$24	$39	2023	2	2025–2034	Shift in expenditures associated with kidney dialysis to expenditures associated with kidney transplantation.
NET BENEFITS:							
Annualized monetized net benefits.	$746	$412	$1,101	2023	2	2025–2034	

Note: primary, low, and high estimates correspond to the mean, 5th percentile, and 95th percentile of the outcomes of a Monte Carlo simulation.

We have developed a comprehensive preliminary economic analysis of impacts that assesses the impacts of the proposed rule, which is available in the docket for this proposed rule Document ID HRSA–2024–0001.

List of Subjects in 42 CFR Part 121

Health care, Hospitals, Transplant centers, Organ transplantation, Reporting and recordkeeping requirements.

[66] U.S. Office of Management and Budget, Office of Information and Regulatory Affairs. ''2018, 2019, and 2020 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act.'' *https://www.whitehouse.gov/wp-content/uploads/2021/01/2018_2019_2020-OMB-Cost-Benefit-Report.pdf.*

Dated: September 6, 2024.

Xavier Becerra,

Secretary.

Accordingly, by the authority vested in me as the Secretary of Health and Human Services, and for the reasons set forth in the preamble, 42 CFR part 121 is proposed to be amended as follows:

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

■ 1. The authority citation for part 121 continues to read as follows:

Authority: Sections 215, 371–77, and 377E of the PHS Act (42 U.S.C. 216, 273–274d, 274f–5); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8, and 1395hh); section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e); and E.O. 13879, 84 FR 33817.

■ 2. In § 121.6, revise paragraph (b) to read as follows:

§ 121.6 Organ procurement.

* * * * *

(b) *HIV.* (1) Organs from donors with human immunodeficiency virus (HIV) may be transplanted only into individuals who—

(i) Are living with HIV before receiving such organ(s); and

(ii)(A) Are participating in clinical research approved by an institutional review board, as defined in 45 CFR part 46, under the research criteria published by the Secretary under subsection (a) of section 377E of the Public Health Service Act, as amended; or

(B) The Secretary has published, through appropriate procedures, a determination under section 377E(c) of the Public Health Service Act, as amended, that participation in such clinical research, as a requirement for transplants of donor organs with HIV, is no longer warranted. The Secretary has determined that participation in such clinical research is no longer warranted for the following categories of transplants:

(*1*) Transplant of a donor kidney with HIV; and

(*2*) Transplant of a donor liver with HIV.

(2) Except as provided in paragraph (b)(3) of this section, the OPTN shall adopt and use standards of quality with respect to donor organs with HIV to the extent the Secretary determines necessary to allow the conduct of research in accordance with the criteria described in paragraph (b)(1)(ii)(A) of this section.

(3) If the Secretary has determined under paragraph (b)(1)(ii)(B) of this section that participation in clinical research is no longer warranted as a requirement for transplants of donor organs with HIV, the OPTN shall adopt and use standards of quality with respect to donor organs with HIV as directed by the Secretary, consistent with 42 U.S.C. 274, and in a way that ensures the changes will not reduce the safety of organ transplantation.

* * * * *

[FR Doc. 2024–20643 Filed 9–11–24; 8:45 am]

BILLING CODE 4150–28–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 64

[GN Docket No. 24–213; MD Docket No. 10–234; FCC 24–85; FR ID 240720]

Improving the Effectiveness of the Robocall Mitigation Database; Amendment of CORES Registration System

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes and seeks comment on procedural measures that would require Robocall Mitigation Database filers to take additional steps to ensure the accuracy of submitted information, potential technical solutions for validating data, accountability measures to ensure and improve the overall quality of submissions in the Robocall Mitigation Database, and generally invites comment on any other procedural steps the Commission could require to increase the effectiveness of the Robocall Mitigation Database as a compliance and consumer protection tool.

DATES: Comments are due on or before October 15, 2024, and reply comments are due on or before November 12, 2024.

ADDRESSES: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated above. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing ECFS: *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8 a.m. and 4 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express must be sent to 45 L Street NE, Washington, DC 20554.

Accessible Formats. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice).

FOR FURTHER INFORMATION CONTACT: For further information about the Notice of Proposed Rulemaking (*NPRM*), contact Erik Beith, Attorney Advisor, Competition Policy Division, Wireline Competition Bureau, at *Erik.Beith@fcc.gov.* For additional information concerning the Paperwork Reduction Act proposed information collection requirements contained in this document, send an email to *PRA@fcc.gov* or contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *NPRM* in GN Docket No. 24–213, MD Docket No. 10–234, released on August 8, 2024. The complete text of this document is available for download at *https://docs.fcc.gov/public/attachments/FCC-24-85A1.pdf.*

Paperwork Reduction Act: The *NPRM* may contain proposed new and revised information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4),