and IMmb meeting the standards in 204.2.0.

* * * * *

507 Mailer Services

* * * * *

5.0 Package Intercept

* * * * *

5.3 Adding Extra Services

[Revise the third sentence in the introductory text of 5.3 to read as follows:]

* * * The relabeled item will be assigned a new barcode applicable to the extra service purchased.* * *

* * * * *

600 Basic Standards for All Mailing Services

601 Mailability

1.0 General Standards

* * * * *

1.2 Overweight Items or Oversize Items

* * * * *

1.2.3 Fee

[Revise the text of 1.2.3 to read as follows:]

Except for an overweight or oversize item discovered and picked up at the same facility where it was entered, the overweight/oversize item fee of $200 will be assessed and must be paid before release of the item. The $200 overweight or oversize item fee may be paid by any authorized retail payment method or through *PostalOne!.*

* * * * *

604 Postage Payment Methods and Refunds

* * * * *

9.0 Exchanges and Refunds

* * * * *

9.2 Postage and Fee Refunds

* * * * *

9.2.4 Postage and Fee Refunds Not Available

Refunds are not made for the following:

* * * * *

[Revise 9.2.4 by adding an item j to read as follows:]

j. For the Package Intercept per-piece fee once the USPS successfully intercepts the mailpiece (507.5.2) or the Live Animal and Perishable Handling fee once the piece is entered in the network.

* * * * *

609 Filing Indemnity Claims for Loss or Damage

1.0 General Filing Instructions

* * * * *

1.2.2 Eligibilty

Eligibility for mailers to submit claims using the Bulk Indemnity Claims feature is based on the following:

* * * * *

[Revise the text of item b to read as follows:]

b. IMpb and IMmb compliance history.

* * * * *

1.3 Who May File

A claim may be filed by:

* * * * *

[Revise the text of item c to read as follows:]

c. Only the account holder, for USPS Returns packages that are insured as identified by the account holder's mailer identification (MID) and the applicable STC for insurance imbedded into the IMpb and IMmb on the label, and for which the account holder has provided electronic data that supports the value of the merchandise being returned (see 503.4.3.1a).

* * * * *

700 Special Standards

* * * * *

705 Advanced Preparation and Special Postage Payment Systems

* * * * *

18.0 Priority Mail Express Open and Distribute and Priority Mail Open and Distribute

* * * * *

18.5 Preparation

* * * * *

18.5.7 Address Label Service Barcode Requirement

[Revise first and third through fifth sentences in the introductory text of 18.5.7 to read as follows:]

An electronic service barcode must include an Intelligent Mail package barcode (IMpb) and Intelligent Mail matrix barcode (IMmb) (eVS approved mailers) symbology for Priority Mail Express Open and Distribute, and the IMpb and IMmb symbology for Priority Mail Open and Distribute in the address label.* * * * * * Priority Mail Express Open and Distribute IMpb and IMmb labels must include service type code ''723.'' For Priority Mail Open and Distribute, the IMpb and IMmb must include service type code ''123.'' The human-readable text ''USPS SCAN ON ARRIVAL'' must appear above the IMpb barcode.* * *

* * * * *

[Add an IMmb in the address block to the left of the delivery address to the label graphics in Exhibits 18.5.8 through 18.5.12.]

* * * * *

Index

* * * * *

I

* * * * *

Intelligent Mail

* * * * *

[Revise the ''Intelligent Mail'' entry by alphabetically adding the following:]

matrix barcode, 204.2.0

* * * * *

Notice 123 (Price List)

[Revise competitive prices as applicable.]

* * * * *

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2024–27463 Filed 11–26–24; 8:45 am]

BILLING CODE 7710–12–P

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: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) amends 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 kidneys 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 determines that participation in such clinical research should no longer be a requirement for transplantation of kidneys and livers from donors with HIV to recipients with HIV. This final rule serves as publication of the

Secretary's determination and amends the regulations to reflect this determination. This final rule also serves as publication of the Secretary's direction to the Organ Procurement and Transplantation Network (OPTN) to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that are 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: This rule is effective November 27, 2024.

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

On September 12, 2024, HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (89 FR 74174) proposing both that the Secretary of HHS determine that participation in clinical research should no longer be required for transplantation of kidneys and livers from donors with HIV to recipients with HIV, and that the HHS regulations at 42 CFR part 121 implementing the HOPE Act be amended consistent with this proposed determination. The NPRM provided for a 30-day comment period, and HHS received 56 comments raising a variety of issues. HHS has carefully considered all comments in developing this rule, as outlined in section III, below, and presents a summary of all significant comments and Departmental responses.

II. Background

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 CFR part 121. The OPTN is also charged with developing policies on many subjects related to organ donation, procurement, and transplantation, which include establishing standards of quality pertaining to organs procured for use in transplantation. 42 U.S.C. 274(b)(2)(E).

B. HOPE Act Requirements and Implementation

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 scientific 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.[1] 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 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, the National Institutes of Health (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.[2]

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 antiretroviral therapy (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. 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

[1] **Federal Register**. Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act. 80 FR 26464 (May 8, 2015). *https://www.federalregister.gov/documents/2015/05/08/2015-11048/organ-procurement-and-transplantation-implementation-of-the-hiv-organ-policy-equity-act.*

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

methods of improving organ allocation) providing standards for transplant hospitals conducting HOPE Act transplants.[3] The OPTN expanded the variance in 2019 to include all solid organs,[4] and extended the variance through January 2026, to provide for the gathering of data and subsequent evaluation of the outcomes of HOPE Act transplants.[5]

C. Review of Research Results

The Secretary, in conjunction with the OPTN, reviewed 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 allowed 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.[6] 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 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 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 found 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.[7] Rates of opportunistic infections and infections requiring hospitalization post-transplant did not differ significantly across the study arms. Rejection 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 statistically significant. The insignificance of the result is due, in part, to the relatively small sample size. 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 higher rejection rates in HIV allografts. 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 merited further investigation.

A separate pilot study 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.)

[3] 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.*

[4] 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.*

[5] 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.*

[6] 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.*

[7] 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.

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 increases among HOPE Act liver transplant recipients in mortality, cytomegalovirus (CMV) viremia, infectious hospitalizations, and cancer, were observed. 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.[8]

Ongoing Clinical Trials

The OPTN further considered the progress of an NIH-funded study on HOPE Act kidney transplants that was ongoing at the time of the OPTN's analysis. The NIH-funded U01 HOPE Act kidney transplant clinical trial was designed to analyze rejection and long-term outcomes of kidney transplantation for recipients with HIV. While the study was subsequently expanded, at the time of the OPTN's consideration the study was designed to 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.[9] The results from this clinical trial were published in October 2024 and are described in section 3, ''Additional Research Results Published Subsequent to Issuance of the NPRM,'' below. Of note, these investigators were awarded an expansion grant to evaluate longer-term outcomes in HOPE Act kidney transplants.

Similarly, the OPTN considered the progress of an ongoing U01 HOPE Act liver transplant clinical trial 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,[10] reaching target enrollment, and now is in the phase of patient follow-up. 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.[11] 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.[12]

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 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.[13] 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.[14] [15]

2. Additional Research Results Published Subsequent to the OPTN Assessment

Prior to publication of the NPRM, the Secretary further considered additional research published providing more evidence for the safety of organ transplantation from donors with HIV to recipients with HIV. In general, this research demonstrates that the safety and outcomes of kidney and liver HOPE Act transplants are well established, with over 517 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,

[8] 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.

[9] 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.*

[10] 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.*

[11] 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.

[12] 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.

[13] 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.*

[14] 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.*

[15] 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.

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 organs from donors with HIV in recipients with HIV. Further, the study also found that there were no major differences in 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.[16]

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.[17] 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.[18] 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 end stage renal disease (ESRD) have higher mortality than people with ESRD who are not also living with HIV,[19] in HHS's view, this data illustrates the benefit of HOPE Act kidney transplants for this vulnerable population.

The HOPE in Action Consortium also has published information 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.[20]

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 three heart transplants have been conducted, including one heart-kidney transplant.[21] [22] No HOPE Act transplants have been recorded among recipients in need of other organs. 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. Additional Research Results Published Subsequent to Issuance of the NPRM

Since publication of the NPRM, results from a new, groundbreaking study were published in October 2024.[23] In the largest prospective, observational, multicenter study to date, researchers compared transplantation of kidneys at 26 U.S. centers from deceased donors with HIV and donors without HIV to recipients with HIV. The study enrolled 408 transplantation candidates, of whom 198 received a kidney from a deceased donor; 99 received a kidney from a donor with HIV and 99 from a donor without HIV. This study was larger than the HOPE Act pilot study, described above, and was designed to assess whether kidney transplantation from donors with HIV to recipients with HIV would be noninferior to transplantation from donors without HIV. The study further assessed safety and post-transplantation complications.

The primary outcome assessed was a safety outcome (a composite of death from any cause, graft loss, serious adverse event, HIV breakthrough infection, persistent failure of HIV treatment, or opportunistic infection) for noninferiority (margin for the upper bound of the 95% confidence interval, 3.00). Researchers found an adjusted hazard ratio of 1.00 for the primary composite outcome, demonstrating noninferiority of kidney transplantation from donors with HIV as compared to kidney transplantation from donors without HIV.

Secondary outcomes included overall survival, survival without graft loss, rejection, infection, cancer, and HIV superinfection. The following secondary outcomes were similar whether the donor had HIV or not: overall survival at 1 year (94% vs. 95%) and 3 years (85% vs. 87%), survival without graft loss at 1 year (93% vs. 90%) and 3 years (84% vs. 81%), and rejection at 1 year (13% vs. 21%) and 3 years (21% vs. 24%).

The incidence of serious adverse events, infections, and cancer was similar in all groups studied. Of note, the incidence of HIV breakthrough infection was approximately three times higher among HOPE Act transplants (incidence rate ratio, 3.14; 95% CI, 1.02 to 9.63), which the researchers attributed to non-adherence to antiretroviral therapy. In all participants with HIV breakthrough infection, viral suppression was regained. A single case of potential HIV superinfection or dual infection occurred among the 58 recipients in this group, without HIV breakthrough infection or clinical consequences.

[16] 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.

[17] 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.

[18] 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.

[19] 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.

[20] 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.

[21] 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.*

[22] 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.

[23] C.M. Durand, A. Massie, S. Florman, T. Liang, M.M. Rana, R. Friedman-Moraco, A. Gilbert, P. Stock, S.A. Mehta, S. Mehta, V. Stosor, M.R. Pereira, M.I. Morris, J. Hand, S. Aslam, M. Malinis, G. Haidar, C.B. Small, C.A.Q. Santos, J. Schaenman, J. Baddley, D. Wojciechowski, E.A. Blumberg, K. Ranganna, O. Adebiyi, N. Elias, J.A. Castillo-Lugo, E. Giorgakis, S. Apewokin, D. Brown, D. Ostrander, Y. Eby, N. Desai, F. Naqvi, S. Bagnasco, N. Watson, E. Brittain, J. Odim, A.D. Redd, A.A.R. Tobian, and D.L. Segev, for the HOPE in Action Investigators. Safety of Kidney Transplantation from Donors with HIV. New England Journal of Medicine. 2024 Oct 17; 391(15): 1390–1401.

Among the acknowledged limitations of this study are the lack of true randomization, which the authors note was not possible due to the U.S. national organ allocation process. The authors further note that study participants were equally eligible for a kidney from a donor with or a donor without HIV, and that study group assignment was determined according to whichever organ was available first. The study group whose donors did not have HIV served as a control group and included 27 donors who were treated as having HIV during allocation but did not; in the authors' estimation, recipients of kidneys from these donors represent an ideal counterfactual control group. Immunosuppression and prophylaxis were heterogeneous; however, these factors were balanced between the two groups and reflect real-world practice, which the authors assert increases the generalizability of the study results.

This study is an important addition to the evidence base for HOPE Act kidney transplants in that the finding that kidney transplantation from donors with HIV was noninferior to kidney transplantation from donors without HIV with respect to the primary safety outcome, and that the incidence of serious adverse events, infections, surgical or vascular complications, and cancer was similar in the two groups, supporting the safety of HOPE Act kidney transplants.

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

The Secretary also considered the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recommendation that the Secretary eliminate research and IRB requirements for all HOPE Act transplants. The ACBTSA working group developing this recommendation considered the OPTN recommendation and the results of relevant scientific research. While the ACBTSA working group proposed that the full committee recommend that the Secretary eliminate research and IRB requirements for all HOPE Act transplants, the working group expressed concern about the elimination of research and IRB requirements for non-kidney and non-liver HOPE Act transplants,[24] and whether there was sufficient data collected on other organs to justify a full adoption of 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.

Upon review of the OPTN, ACBTSA and BOTSEC recommendations, and in consideration of the results of relevant scientific research, the Secretary proposed to determine that the research and IRB requirements for kidney and liver HOPE Act transplants are no longer warranted. The NPRM incorporated this approach, publishing the Secretary's proposed determination for comment, and proposing regulatory changes to exempt HOPE Act kidney and liver transplants from research and IRB requirements. In an effort to avoid the use of stigmatizing language, the NPRM further proposed wording changes to references to persons, donors, and recipients with HIV, and organs from individuals with HIV.

III. Discussion of Public Comment

HHS received 56 comments from individuals and organizations involved in healthcare, organ transplantation, HIV advocacy, health equity, LGTBQIA+ health, and HOPE Act clinical research. The comments received expressed overwhelming support for the finalization of this rule. A total of 55 of the 56 commenters expressed support for the proposed rule. One commenter did not support the proposed rule. Additional consideration was given to comments that were expressed by multiple individuals and entities. HHS has considered all of the comments, and, in response to comments regarding the use of non-stigmatizing language, made changes to the final rule as suggested by commenters.

Themes identified in many comments include that the proposed rule, if finalized, could reduce morbidity and mortality for people with HIV, reduce barriers to organ transplantation, increase organ utilization, reduce wait times for people on organ transplant wait lists, and reduce stigma and discrimination associated with HIV. One commenter indicated that, given that only 31 of the 250 transplant centers in the U.S. currently participate in HOPE Act clinical trials, access to these vital transplants is geographically limited: the proposed rule would encourage more transplant centers to offer HOPE Act transplants, enabling more equitable access to life-saving care for people with HIV across the country and helping to generate additional clinical data to enhance understanding and inform best practices in transplant care for people with HIV. In addition, numerous commenters noted that research has sufficiently demonstrated that HOPE Act kidney and liver transplants are both safe and effective.

The NPRM specifically invited public comment on the future Secretarial direction to the OPTN to revise the standards of quality concerning kidneys and livers from donors with HIV. Some commenters provided specific suggestions for the Secretary's direction, and other comments received appear relevant to HHS's consideration as to the content of the direction to the OPTN. These comments are noted below in both the subheading discussing the comments specifically provided on the content of the direction to the OPTN, and the subheadings relating to the subject matter of the comment. HHS has considered these comments in the development of the Secretary's direction to the OPTN, which is provided in section V, ''Implementation Considerations,'' below.

Multiple commenters also provided specific suggestions for the content of the revised NIH Research Criteria, and other comments received appear relevant to the content of the Research Criteria. These comments are noted below in both the subheading discussing the comments specifically provided on the Research Criteria, as well as in the subheadings relating to the subject matter of the comment when the commenter did not specifically reference the Research Criteria. All comments relating to the content of the revised Research Criteria were provided to NIH for consideration in the development of the revised Research Criteria.

Detailed descriptions of comments on specific aspects of the NPRM preamble and the proposed regulation, and HHS's responses to these comments, are provided below.

[24] 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.*

Removal of Research and IRB Requirements for All Organs

Several commenters suggested that the Secretary should consider in this rule, or in a future rulemaking, the removal of research and IRB requirements for all HOPE Act organ transplants instead of removing research and IRB requirements only for kidney and liver transplants. Some of these commenters referenced the October 2021 letter from the OPTN to the Secretary providing that the OPTN had not identified any patient safety concerns involving HOPE Act transplants and that no research protocols applicable to HOPE Act transplants had been stopped, paused, or substantially altered due to patient safety concerns.[25] Many of these comments suggested that the available data was sufficient to prove the safety and efficacy of HOPE Act transplantation for all organ transplants, not only kidney and liver transplants. Others suggested that HHS should continue supporting research on HOPE Act transplants with the goal of generating sufficient evidence to make the case for a future Secretarial determination and rulemaking process that would remove the research and IRB requirements for all HOPE Act transplants.

HHS response: In the process leading up to the development of the NPRM, the Secretary considered whether to eliminate research and IRB requirements for all HOPE Act transplants. As a part of this process, the Secretary considered the October 2021 communication from the OPTN referenced by commenters, recommendations of advisory bodies, and research results and outcomes data on HOPE Act transplants. The vast majority of this data was generated from kidney and liver transplants, and, as discussed in the NPRM preamble, the Secretary notes the limited evidence demonstrating safety and efficacy of non-kidney and non-liver HOPE Act transplants. In order to lift the research and IRB requirements for HOPE Act transplants, the HOPE Act requires that the Secretary must determine that participation in clinical research is no longer warranted. 42 U.S.C. 274(b)(3)(B)(ii). In the absence of research results and robust outcomes data 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. For this reason, the NPRM proposal to lift the research and IRB requirements only for HOPE Act kidney and liver transplants is incorporated in this final rule. As required by the HOPE Act, the Secretary will periodically review the results of additional scientific research relevant to transplants of organs other than kidneys and livers, and will reevaluate in the future whether the evidence is robust enough to demonstrate that other types of HOPE Act transplants need not be conducted in the research context. HHS makes no changes to the regulatory proposal in response to these comments.

Language Regarding HIV

Many commenters expressed support for the proposed revisions to the regulatory language used when referencing people, donors, and recipients with HIV. In general, commenters suggested that the proposed changes are more respectful, reflect a person-centered approach, and help to combat stigma associated with HIV. Others noted that these wording changes help to create a more inclusive healthcare environment.

One commenter requested that the proposed modification to 42 CFR 121.6 regarding references to donor organs be changed from ''donor organ(s) with HIV'' to ''organ(s) from donors with HIV.'' The commenter stated that, in their view, the term ''organs from donors with HIV'' is accurate and precise, stigma-reducing, and reflects a person-first approach in describing these donated organs.

HHS response: HHS appreciates this feedback, and includes the regulatory revisions in this final rule as proposed with regard to references to people, donors, and recipients with HIV. Further, HHS concurs with the suggested revision provided by the commenter with respect to the references to donor organs, and has incorporated this suggested revision and other similar revisions in the final rule at 42 CFR 121.6(b)(1)(ii)(B) introductory text, (b)(1)(ii)(B)(*1*) and (*2*), and (b)(2).

Ongoing Data Monitoring

Multiple commenters expressed support for efforts to monitor outcomes of HOPE Act transplants, both for patient safety and to develop evidence for the safety and efficacy of HOPE Act transplants.

Commenters addressing patient safety indicated that while the proposed rule may streamline the transplant process and increase the availability of organs, patient safety must be the top priority and rigorous safety standards must continue to apply. Several commenters noted that areas needing further attention, such as monitoring for rejection, malignancy, and infection, do not overshadow the overall favorable outcomes for HOPE Act kidney and liver transplants. Commenters emphasized the importance of continued monitoring of outcomes for these transplants by the OPTN, and that transparency and public communication of these outcomes are critical to maintaining trust and ensuring the ongoing success of HOPE Act transplant programs. Commenters indicated that application of the NIH Research Criteria has provided essential protections with regard to outcomes monitoring for HOPE Act kidney and liver transplants, and urged continued monitoring of HOPE Act transplants to ensure these protections are maintained.

Other commenters expressed that data monitoring could help HOPE Act transplant recipients and HOPE Act living donors who may need to be monitored for the development of chronic or end-stage conditions. For example, one commenter noted that living kidney donors ''are already at higher risk of kidney disease and will now only have one kidney.''

Commenters addressing evidence development noted that monitoring and evaluation of HOPE Act transplants may help develop evidence that will inform future policy, including a potential future implementation of the HOPE Act to remove research and IRB requirements for all HOPE Act organ transplants.

Several commenters indicated that current data monitoring requirements applicable to all organ transplants are sufficient. One commenter indicated that there is no reason to continue monitoring HOPE Act kidney and liver transplant outcomes above and beyond the baseline safety and outcomes monitoring for all organ transplants in the United States. One commenter indicated that the OPTN structure and outcome data collected are sufficient in their current state to provide oversight for all organs. Another commenter indicated comfort with appropriate oversight and data management by the organizations designated to oversee transplant services on a national level, which could include comprehensive reporting systems to track outcomes and address any issues promptly. The commenter further expressed an expectation that this information be made available to the public is a transparent manner.

HHS response: HHS notes that the final rule does not affect existing data

[25] 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.*

monitoring or evaluation requirements for HOPE Act transplants, as these are determined by OPTN policy and the NIH Research Criteria. HHS agrees that patient safety remains a paramount concern and that appropriate safety standards apply to protect organ donors and transplant recipients. Further, HHS expects to utilize data on HOPE Act transplant outcomes in its ongoing evaluation of the HOPE Act. These comments were provided to the NIH working group for consideration in the development of revisions to the Research Criteria. Further, HHS considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV. HHS makes no changes to the regulatory proposal in response to these comments.

Standards for Transplant Centers Performing HOPE Act Transplants

Several commenters provided suggestions for transplant centers that are seeking to participate in HOPE Act transplants. One commenter requested that HHS evaluate all outstanding requests by transplant centers to participate in HOPE Act transplants, and approve qualifying transplant centers as soon as possible to both expand access to care and to generate additional data on the HOPE Act transplants they perform. The commenter further requested that HHS explore providing grants designed to build the capacity at transplant centers such that more transplant centers will be able to meet the minimum requirements necessary to become HOPE Act transplant centers.

HHS response: Thank you for these suggestions. While no changes have been made to the regulatory proposal in response to these comments, HHS will consider these suggestions in the Department's ongoing approach to implementation of the HOPE Act.

Informed Consent and Autonomy of Transplant Recipients

Some commenters expressed the desire that, if HHS finalizes the proposed rule, that HHS take steps to prioritize ethical considerations relevant to the autonomy of donors and recipients. In particular, commenters asked that transplant centers maintain meaningful processes to provide patients with the opportunity to provide informed consent, and that transplant candidates with HIV retain the option to elect a non-HOPE Act transplant instead of a HOPE Act transplant.

HHS response: This rule does not affect existing OPTN policies that require that informed consent is obtained from all transplant candidates, including HOPE Act transplant candidates,[26] or the informed consent policies or practices at hospitals providing clinical care to potential organ donors, OPOs, or individual transplant centers. HHS supports retaining the existing approach in OPTN policy that requires informed consent.

Further, existing OPTN policies do not prohibit transplant candidates eligible for a HOPE Act transplant to choose a non-HOPE Act transplant.[27] There are no revisions made in this rule that would force a transplant candidate to receive an organ from a donor with HIV. HHS supports retaining the existing approach in OPTN policy that permits transplant candidates eligible for a HOPE Act kidney or liver transplant to choose a non-HOPE Act kidney or liver transplant.

HHS considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV, as provided below in this preamble in the discussion of implementation considerations. HHS makes no changes to the regulatory proposal in response to these comments.

Education

Commenters expressed the desire for additional educational efforts regarding HOPE Act transplantation. Some commenters suggested that HRSA collaborate with the OPTN and work with OPOs to ensure that transplant centers are making compassionate efforts to seek authorization from potential kidney donors with HIV. Commenters further suggested that HRSA partner with the Centers for Medicare & Medicaid Services (CMS) to ensure that donor hospitals recognize every opportunity for organ donation for patients with an HIV-positive diagnosis and make referrals to the local OPO for an organ donation evaluation as mandated by the CMS Conditions of Participation. Other commenters asked for educational efforts aimed at people with HIV, healthcare professionals, students of health sciences, transplant centers, OPOs, and the public at large to increase awareness of the HOPE Act and opportunities to elect organ donation regardless of HIV status.

HHS response: HHS is supportive of any and all efforts to increase awareness and education about HOPE Act transplants, opportunities for persons with HIV to participate as organ donors, and transplant candidates with HIV to receive a HOPE Act transplant. While HHS is not making any revisions to the regulatory proposal in response to these comments, HHS will consider additional educational efforts along the lines of those suggested by the commenters.

NIH Research Criteria

Several commenters provided specific suggestions for the content and development of the revised NIH Research Criteria:

- Commenters requested the elimination of the current requirement that a transplant team perform at least five transplants within a four-year period between any donor and a recipient with HIV for all organs, as, in the commenters' estimation, this requirement is not necessary for organs from donors with HIV to be used safely.
- Commenters suggested that each transplant team should include infectious disease specialists with expertise in HIV care.
- One commenter requested the elimination of the biopsy requirement.
- One commenter noted that, in revising the Research Criteria, NIH should both maintain the strong patient safety record for HOPE Act transplants, while actively seeking to reduce burdens that may be slowing the establishment of non-kidney and non-liver HOPE Act transplant programs.
- One commenter requested that NIH include people with HIV, HIV researchers, physicians, and healthcare providers in the process of developing revised Research Criteria, and indicated that these individuals can provide invaluable insights that can only come from lived experience.

HHS response: HHS appreciates these suggestions, and agrees that these comments are relevant to the content of the NIH Research Criteria. These comments were provided to the NIH working group for consideration in the development of revisions to the Research Criteria. HHS makes no changes to the regulatory proposal in response to these comments.

Secretarial Direction to the OPTN

While multiple commenters provided suggestions that appear relevant to the Secretary's future direction to the OPTN to revise the standards of quality concerning kidneys and livers from donors with HIV, only a few commenters specifically referenced the

[26] Organ Procurement and Transplantation Network. OPTN Policies. Updated October 31, 2024. *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[27] Organ Procurement and Transplantation Network. OPTN Policies. Updated October 31, 2024. *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

content of the Secretarial direction and provided recommendations. One commenter indicated that they defer to health care professionals as to the content of such direction, and further urged HHS to make sure that the final OPTN policies do not create additional barriers or lead to unintended consequences that make it more difficult for individuals to access these organs. One commenter requested that the direction to the OPTN require intensive and multi-disciplinary counseling and discussions to be conducted with the solid organ recipient, with ongoing care before, during, and after the transplant, to ensure that solid organ recipients understand the complexities of the transplant procedure while also receiving the emotional and physical care they need throughout the entirety of the process. The commenter further noted the opportunity for the OPTN to define transplant program collaboration on a more formal basis, recommending that the structure of the transplant team include nephrologists and/or hepatologists, infectious diseases experts, and transplant pharmacy members, and that requirements be instituted for providing counseling or any specific transplant training recommendations for infectious disease experts.

The commenters who provided views and suggestions that are relevant to the Secretary's direction to the OPTN, while not specifically referencing the content of the Secretary's direction, generally indicated that the current requirements applicable to all organ transplants are sufficient to appropriately ensure the safety of HOPE Act kidney and liver transplants conducted outside of the research context. One commenter indicated that there is no reason to impose special monitoring requirements for HOPE Act kidney and liver transplant outcomes, as appropriately protective standards are already included in the baseline safety and outcomes monitoring for all organ transplants in the United States. One commenter indicated that the OPTN structure and outcome data collected are sufficient in their current state to provide appropriate oversight for all organ transplants, regardless of whether the transplant involves organs from donors with HIV to recipients with HIV. Another commenter indicated comfort with appropriate oversight and data management by the organizations designated to oversee transplant services on a national level, indicating that such oversight may include stringent medical protocols, regular follow-ups, and comprehensive reporting systems to track outcomes and address any issues promptly. The commenter further expressed an expectation that safety and outcomes information be made available to the public is a transparent manner.

One commenter noted that HHS stated in the NPRM that scientific evidence demonstrates that transplants of kidneys and livers from donors with HIV to recipients with HIV are safe and effective. Given this view, the commenter opined that the current clinical standards of care for non-HOPE Act organ transplants are sufficient to apply to transplants of all kidneys and livers, of any HIV serostatus. The commenter further expressed that additional scrutiny of transplants of kidneys and livers from donors with HIV to recipients with HIV could be viewed as discrimination against recipients with HIV who are willing to accept offers of an organ from a donor with HIV, and infringes on patient autonomy. The commenter noted that the OPTN already is responsible for safety and outcomes monitoring for transplants that involve donors or recipients with viruses other than HIV, including cytomegalovirus, Epstein-Barr virus, hepatitis B and C viruses, and severe acute respiratory syndrome coronavirus 2.

HHS response: HHS appreciates all of the comments and suggestions regarding the content of the Secretary's direction to the OPTN. HHS has carefully considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV. As discussed below in section V, ''Implementation Considerations,'' through publication of this final rule, the Secretary directs the OPTN to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that, from the OPTN's expertise, will not reduce the safety of HOPE Act kidney and liver transplants, provide appropriate oversight for these transplants, and require sufficient data collection and outcomes monitoring.

Health Equity and Patient Experience

Many comments positively noted the health equity component of the proposed rule and the potential impact to populations that are disproportionately impacted by HIV and end-stage chronic diseases. Several commenters requested that HHS consider the insights and experiences of HOPE Act patients in this and future rulemaking efforts.

HHS response: We agree. HHS supports efforts to better address health equity in organ transplantation and believes this rule will help to increase access to care among populations that are disadvantaged. HHS also is supportive of efforts to incorporate patient experience into policy, and we have received, and considered, comments from HOPE Act patients during this rulemaking process, including a comment from a self-identified living donor of a kidney used in a HOPE Act transplant. HHS makes no changes to the regulatory proposal in response to these comments.

Approach to Patient Care

Several commenters suggested changes to clinical care standards for HOPE Act transplant patients. One commenter requested that the Department encourage transplant centers to incorporate syndemic care approaches to address the complex needs of people with HIV. Syndemic care aims to provide more holistic service delivery to prevention and care, including by addressing the social determinants of health that allow for health conditions to cluster and interact. Several commenters requested that additional safety protocols be developed for transplant centers, such as post-operative care guidelines for HOPE Act transplant recipients.

HHS response: HHS is supportive of efforts to incorporate syndemic care approaches within the organ transplantation domain. Regarding the establishment of additional safety protocols for transplant centers, currently safety protocols beyond those included in the NIH Research Criteria are determined by individual transplant centers. These comments were provided to the NIH working group for consideration in the development of revisions to the Research Criteria. Further, HHS considered these comments in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV, as provided below in the discussion of implementation considerations. HHS makes no changes to the regulatory proposal in response to these comments.

Addressing Diverse Needs

Several commenters requested that HHS consider the unique challenges of patients who are Black, Indigenous, and people of color and patients living in rural areas. A commenter indicated that post-transplant care is essential for

positive patient outcomes and factors such as implicit bias in medical settings, socioeconomic disparities, and geographic limitations frequently hinder equitable access to post-transplant care, especially for people experiencing both geographic isolation and medical racism. Long travel distances to transplant centers and lacking local healthcare options can impede consistent follow-up care and medication compliance.

HHS response: HHS is supportive of efforts to improve health equity in organ transplantation and believes this rule will contribute to improving access to care for patients who are Black, Indigenous, and people of color and patients living in rural areas by allowing HOPE Act kidney and liver transplants to be conducted at any transplant center in the United States. HHS makes no changes to the regulatory proposal in response to this comment.

Standards for Transplant Candidates

One commenter noted his opposition to lengthy sobriety requirements for liver transplant candidates.

HHS response: Currently, sobriety requirements for transplant candidates are determined by individual transplant centers. This comment was provided to the NIH working group for consideration in the development of revisions to the Research Criteria. Further, HHS considered this comment in developing the Secretary's direction to the OPTN to revise the OPTN standards of quality embodied in OPTN policy regarding organs from donors with HIV, as provided below in this preamble in the discussion of implementation considerations. HHS makes no changes to the regulatory proposal in response to this comment.

Future Research on HOPE Act Transplants

Multiple commenters expressed support for additional research evaluating the safety and efficacy of HOPE Act transplants. One commenter suggested that the experience of HOPE Act transplant patients should help inform the direction of future research on HOPE Act transplants.

HHS response: HHS is supportive of additional research evaluating the safety and efficacy of HOPE Act transplants, and considering patient experiences in informing the direction of future research. While no changes are made to the regulatory proposal in response to these comments, HHS will consider these comments in further efforts to implement the HOPE Act.

Beyond Scope

Some commenters provided comments or made suggestions that are beyond the scope of the proposed rule.

One commenter requested that HHS establish a program to provide technical assistance to state, local, and tribal health departments with the goal of adopting policies to prevent health information from being used in a criminal, civil, or immigration legal proceeding.

One commenter noted that none of the other comments provided on the NPRM highlight that there will be a conflict between a majority of expressly prohibitive or potentially permissive State laws and expressly permissive Federal law when this proposed rule is finalized. The commenter indicated that State laws that are silent on or prohibitive of organ transplantation between people diagnosed with HIV can and do preclude performance of HOPE Act transplants within a given jurisdiction regardless of permissive Federal laws, and despite Congress and Federal regulators having the authority to preempt state and local health laws.

Multiple commenters noted that State criminal laws that prohibit persons with HIV for donating or attempting to donate organs, blood, tissue, and other bodily fluids are a legal barrier to implementation of the HOPE Act.

HHS response: As these comments are not within the scope of the proposed rule, these comments have not altered HHS's proposed approach to lifting the research and IRB requirements for HOPE Act kidney and liver transplants.

Opposition

One commenter opposed the proposed rule, suggesting that organs from donors with HIV are not the same as organs from donors without HIV, and expressing concern regarding the transmission of HIV through organ transplantation to recipients without HIV.

HHS response: HHS notes that there have been no reported cases of inadvertent HIV transmission resulting from HOPE Act transplants. Further, under the requirements of the HOPE Act, transplantation of organs from donors with HIV to recipients without HIV is prohibited. HHS makes no changes to the regulatory proposal in response to this comment.

IV. Secretarial Determination

The Secretary has reviewed the recommendations of the OPTN, the ACBTSA, and the BOTSEC on implementation of the HOPE Act, 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, and public comment received on the NPRM. 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 determines that participation in clinical research, and 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 publication of this final rule, the Secretary is lifting the statutory research and IRB requirements for such transplants.

HHS anticipates that the Secretary's determination and publication of this final rule will increase access to kidney and liver transplants by allowing more transplant centers to perform HOPE Act kidney and liver transplants. 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 by some as a barrier to participation in HOPE Act transplant programs, which may impact equity and access to organ transplantation throughout the United States.[28] By eliminating the requirement that HOPE Act kidney and liver transplants are conducted in the research context, HHS expects that a larger number of transplant centers will be able to conduct such transplants. This rule 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.

Further, HHS expects this rule will expand access to organ transplantation for all patients, regardless of their HIV status. When eligible for transplant, a

[28] 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.

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 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.[29] Every 10 minutes another person is added to the waiting list, and nearly 20 people die every day while waiting for a transplant.[30] HHS expects that the Secretary's determination and publication of this rule will improve access to kidney and liver transplants both by increasing the number of kidneys and livers available for transplant, and by allowing more transplant centers to perform HOPE Act kidney and liver transplants. This anticipated positive result is consistent with the Department's commitment to reducing the number of persons on the organ transplant waiting list.

V. Implementation Considerations

A. 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). NIH, in consultation with HRSA and the OPTN, and including the input of other relevant Federal stakeholders, formed a working group to develop revised NIH Research Criteria. The NIH 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 this rule removes HOPE Act kidney and liver transplants from the research context, it is necessary that the revised NIH Research Criteria appropriately address non-kidney and non-liver HOPE Act transplantation.

Further, HHS recognizes the revised NIH Research Criteria should reflect advances in research in the time since HOPE Act transplants began, including the current needs of various entities involved in non-kidney and non-liver 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.

HHS has considered the comments submitted in response to the NPRM that are relevant to the revised NIH Research Criteria, as summarized in the discussion of public comment in section III, *supra.* These comments have been provided to NIH for consideration in developing the revised NIH Research Criteria. HHS will publish updated Research Criteria in the **Federal Register** for public comment.

B. Secretary's Direction To Revise OPTN Policies

As part of the implementation of the Secretary's determination that participation in clinical research as a requirement for transplants of kidneys and livers from persons with HIV is no longer warranted, 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).

In the NPRM preceding publication of this final rule, HHS specifically sought 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 welcomed 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.

As described in the discussion of public comment in section III, *supra,* HHS received multiple comments relating to HHS's consideration as to the direction to the OPTN. The vast majority of commenters agreed that scientific evidence clearly demonstrates that HOPE Act kidney and liver transplants are safe and effective. Many of those commenters indicated that the current requirements applicable to all organ transplants are sufficient to appropriately ensure the continued safety of HOPE Act kidney and liver transplants conducted outside of the research context. HHS has carefully considered all comments received in the development of the Secretary's direction to the OPTN.

Through publication of this final rule, the Secretary directs the OPTN to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that are consistent with 42 U.S.C. 274, and from the OPTN's expertise, will not reduce the safety of HOPE Act kidney and liver transplants, provide appropriate oversight for these transplants, and require sufficient data collection and outcomes monitoring.

In consideration of the public comments received, HHS notes that it may be appropriate for the OPTN to determine that current OPTN policies that are generally applicable to kidney and liver transplants provide appropriate safety and oversight standards for HOPE Act kidney and liver transplants. Alternatively, the OPTN may choose to revise OPTN policies to provide additional standards for HOPE Act kidney and liver transplants.

This rule provides the Secretary's determination that that participation in clinical research as a requirement for transplants of kidneys and livers from persons with HIV is no longer warranted; revises 42 CFR 121.6 to reflect the removal of the statutory research and IRB requirements for HOPE Act kidney and liver transplants; and directs the OPTN to revise its standards of quality with respect to kidneys and livers from donors with HIV consistent with 42 U.S.C. 274 and in a way that ensures the changes will not reduce the safety of organ transplantation policies as required by the HOPE Act. The final implementation step is for the OPTN to adopt and use standards of quality as directed by the Secretary to reflect that HOPE Act kidney and liver transplants no longer are subject to research and IRB requirements.

As was stated in the NPRM, HHS expects that the OPTN will 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 this final rule. As publication of this final rule has obviated current OPTN policies requiring HOPE Act kidney and liver transplants to be conducted in accordance with research and IRB requirements, HHS encourages the OPTN to act expeditiously to revise these policies. This will allow transplant centers that had not

previously been performing HOPE Act kidney and liver transplants in the research context to begin performing HOPE Act kidney and liver transplants in accordance with the revised OPTN policies.

VI. Final Rule Requirements

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

Consistent with the Secretary's determination under the HOPE Act, this rule revises 42 CFR 121.6 to reflect the removal of the statutory research and IRB requirements for kidney and liver HOPE Act transplants. Section 121.6(b)(1)(ii)(B) provides that participation in clinical research is no longer warranted for the following categories of transplants:

- Transplant of a kidney from a donor with HIV; and
- Transplant of a liver from a donor with HIV.

In implementation, this means that HOPE Act kidney and liver transplants will no longer be required to be conducted as research, and instead will be conducted in accordance with OPTN policies applicable to HOPE Act kidney and liver transplants. As noted above, the OPTN may decide that OPTN policies that generally apply to kidney and liver transplants are appropriate to apply to HOPE Act kidney and liver transplants, or may create different policies for HOPE Act kidney and liver transplants.

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 revises all current references in 42 CFR 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, ''organs from donors with HIV'' and specifically ''kidneys from donors with HIV'' and ''livers from donors with HIV.'' Further, HHS revises the current reference in 42 CFR 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.[31] These changed regulatory references are to avoid stigmatizing language, and do not change the groups of people referenced in 42 CFR 121.6.

VII. Effective Date

HHS finds that there is good cause for this rule to be effective upon publication in accordance with 5 U.S.C. 553(d)(3) of the Administrative Procedure Act and 5 U.S.C. 808(2) of the Congressional Review Act.

The waiting list for kidney transplant in the U.S. currently exceeds 88,700 candidates.[32] 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.[33] Most transplant candidates wait years for a kidney transplant, often requiring dialysis or other interventions.

In addition, thousands of Americans suffer from conditions requiring liver transplant. As of November 8, 2024, 13,170 candidates were added to the waiting list in 2024.[34] In 2022, more than 1,031 liver patients died while awaiting transplant, according to the OPTN/SRTR Annual Data Report.[35]

HHS expects that this final rule will have the effect of decreasing the time all candidates for kidney and liver transplants spend on the waiting list, regardless of their HIV status. As described in section IV, above, a transplant candidate with HIV may choose to receive a HOPE Act kidney or liver transplant if an organ from a donor with HIV becomes available, or may choose to wait for an organ from a donor without HIV. Research has demonstrated that candidates with HIV who accept a HOPE Act kidney transplant spend significantly less time awaiting transplant than candidates on the waiting list for an kidney from a donor without HIV. A 2023 study found that median wait time for a HOPE Act kidney transplant was 10.8 months compared to 60.8 months—a 3.3-fold higher rate of transplant compared to non-HOPE Act transplants.[36] When candidates with HIV choose a HOPE Act transplant, this data suggests that this will decrease the time they spent on the waiting list. Additionally, this will have the effect of allowing a candidate further down the waiting list to receive the next available organ from a donor who does not have HIV, both reducing the time that candidate spends waiting for a transplant and decreasing the time all other candidates spend on the waiting list.

Moreover, HHS expects that this final rule also will increase access to organ transplantation. Thirty-one transplant centers are qualified to perform HOPE Act kidney and liver transplants as research in conformance with the requirements of the NIH Research Criteria, while 250 transplant centers operate nationwide. As, pursuant to this rule, HOPE Act kidney and liver transplants no longer need to be conducted as research, it can be reasonably expected that more transplant centers than in the past will be able to offer HOPE Act kidney and liver transplants to appropriate candidates on the transplant center's waiting list. It also is reasonable to expect that if a greater number of transplant centers will be able to offer HOPE Act transplants, this will allow more candidates with HIV on the waiting list to receive HOPE Act kidney and liver transplants.

Lastly, HHS believes that a delayed effective date is unnecessary to afford affected parties a reasonable time to adjust practices in accordance with this rule. From the economic analysis of impacts, provided below in section IX, this final rule will have a minimal direct impact on affected entities with regard to preparing for implementation. The direct effect of this final rule on transplant centers is considered to be limited to the time spent by transplant centers to read and understand the final rule, educate their staff on the content of this final rule, and review and update

[31] 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.

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

[33] Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR). 2022. ''Annual Data Report.'' Accessed November 2024. *https://srtr.transplant.hrsa.gov/ADR/Chapter?name=Liver&year=2022.*

[34] Organ Procurement and Transplantation Network. Dashboard and metrics. *https://optn.transplant.hrsa.gov/data/dashboards-metrics/.* Accessed November 2024.

[35] 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.*

[36] 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.

internal policies. This rule does not impose obligations on transplant centers, and rather increases available flexibilities in that transplant centers are no longer required to conduct HOPE Act kidney and liver transplants in the research context. Further, as described above in section V(B), the final implementation step for HOPE Act kidney and liver transplants to begin occurring outside of the research context is for the OPTN to revise its policies to reflect that HOPE Act kidney and liver transplants no longer are subject to research and IRB requirements. HHS is encouraging the OPTN to act expeditiously to revise these policies, and it is likely that transplant centers will educate their staff and review and update internal policies relevant to the content of this final rule after the OPTN has published its revised policies for HOPE Act kidney and liver transplants. Transplant centers do not have any obligations stemming from this rule until the OPTN revises its policies. In light of this context, a delayed effective date for this rule is unnecessary for implementation purposes.

Given that, and the expected positive effects on time candidates spend on the waiting list and the increase in access to HOPE Act transplants resulting from this rule, pursuant to 5 U.S.C. 553(d)(3) and 5 U.S.C. 808(2) HHS finds that there is good cause for this rule to be effective upon publication.

VIII. Paperwork Reduction Act of 1995

This rule does 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 (OMB). The current data collection requirements in the OPTN final rule approved by 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).

IX. Final Economic Analysis of Impacts

We have examined the impacts of the final 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 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. The regulatory impact analysis indicates, and OIRA has determined, that the final rule is a significant regulatory action under Executive Order 12866, section 3(f)(1), and that it meets the criteria set forth in 5 U.S.C. 804(2) under the Congressional Review Act.

The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their regulatory proposals on small entities. Because the impacts on kidney and liver transplants are small relative to the number of transplants performed annually, and because the economic impacts on affected small entities are small relative to the average payroll of firms in the smallest enterprise size category, HHS certifies that the final 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 final 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, in the aggregate, or by the private sector. Each agency issuing a final rule with relevant effects over that threshold must also seek input from State, local, and tribal governments. The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is $183 million, reported in 2023 dollars. The final rule will not result in an unfunded mandate in any year that meets or exceeds this amount.

The final rule removes the current research and IRB requirements for the transplantation of kidneys and livers from donors with HIV. We have assessed the likely impacts of the final rule, and report in the regulatory impact analysis (RIA) several sources of monetized, quantified, and unquantified benefits, costs, or transfers. Most of the monetized or quantified impacts relate to the incremental increases in the number of kidney and liver transplants that will be performed annually as a result of the final rule.

We report monetized benefits from increases in life expectancy for both kidney and liver transplant recipients; and for kidney transplant recipients, we also report monetized benefits from quality-of-life improvements and time savings from fewer kidney dialysis visits. We also anticipate quality-of-life improvements for liver transplant recipients, and quantify the number of people affected who might experience those benefits. We also identify several sources of unquantified benefits, which could potentially be quantified through additional research or data, including time savings for caregivers, and cost savings for transplant centers from removing the research and institutional review board requirements. We also identify difficult-to-quantify benefits associated with revising vocabulary and phrases that some people find stigmatizing through adoption of language that is intended be respectful of people living with HIV, and living and deceased donors with HIV. These changes may result in people living with HIV experiencing more inclusive interactions when accessing healthcare, generating additional benefits beyond the increases in life expectancy and improvements in quality of life from improved access to liver and kidney transplantation.

We report monetized costs from increases in medical expenditures associated with organ transplantation; for kidney transplants, we report net costs that account for reductions in medical expenditures associated with kidney dialysis. We report this shift in expenditures from kidney dialysis to kidney transplantation as a monetized transfer. We also monetize the opportunity costs of the time spent by transplant centers reading and understanding the final rule, reviewing policies and procedures, and training staff.

Table 1 summarizes our estimates of the benefits, costs, and transfers of the final rule, annualizing impacts over a 10-year analytic time horizon covering 2025 through 2034 using a 2 percent real discount rate, and reporting all

monetary estimates in constant 2023 dollars. Annualized benefits range from $381 million to $858 million, with a primary estimate of $612 million; costs range from $73 million to $92 million, with a primary estimate of $83 million; and transfers range from $24 million to $37 million, with a primary estimate of $30 million. Table 1 also reports our estimates of the annualized net benefits of the final rule, which range from $301 million to $772 million, with a primary estimate of $530 million. The RIA concludes that the monetized net benefits, combined with the quantified, but non-monetized, and unquantified impacts, indicate that the final rule is highly likely to generate net benefits to society. This finding is further supported through additional quantitative assessments of uncertainty and sensitivity analyses contained in the RIA. The full RIA is available in the docket for this final rule at *https://www.regulations.gov/docket/HRSA-2024-0001/document.*

TABLE 1—SUMMARY OF IMPACTS OF THE FINAL 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.	$612	$381	$858	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.	72	64	81	People affected	2	2025–2034	Improved quality of life for liver transplant recipients.
Unquantified benefits						2025–2034	Time savings for caregivers; cost savings for transplant centers from removing the research and institutional review board requirements; difficult-to-quantify benefits associated with stigma-reducing terminology.
COSTS							
Annualized monetized costs.	83	73	92	2023	2	2025–2034	Medical expenditures associated with transplantation; time spent by transplant centers to read and understand the final rule, review policies and procedures, and train staff.
TRANSFERS							
Annualized monetized transfers.	30	24	37	2023	2	2025–2034	Shift in expenditures from kidney dialysis to kidney transplantation.
NET BENEFITS							
Annualized monetized net benefits.	530	301	772	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.

List of Subjects in 42 CFR Part 121

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

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 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, 371–377, 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 transplantation of organs from donors 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 kidney from a donor with HIV; and

(*2*) Transplant of a liver from a donor 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 organs from donors 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 transplantation of organs from donors with HIV, the OPTN shall adopt and use standards of quality with respect to organs from donors 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.

* * * * *

Dated: November 19, 2024.

Xavier Becerra,

Secretary.

[FR Doc. 2024–27410 Filed 11–26–24; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 412

RIN 0970–AD10

Investigations of Child Abuse and Neglect Rule

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period (IFR).

SUMMARY: This IFR describes how ORR shall investigate and substantiate allegations of child abuse and neglect occurring in certain ORR care provider facilities, and maintain a registry of perpetrators relating to certain sustained allegations.

DATES: This IFR is effective December 27, 2024. Comments on this IFR must be received on or before January 27, 2025.

ADDRESSES: You may send comments, identified by [docket number and/or Regulatory Information Number (RIN)], by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: UCPolicy-RegulatoryAffairs@acf.hhs.gov.* Include [docket number and/or RIN] in the subject line of the message.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Toby Biswas, Director of Policy, Division of Unaccompanied Children Policy, Unaccompanied Children Bureau, Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services, Washington, DC, (202) 205–4440 or *UCPolicy-RegulatoryAffairs@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Public Participation

ORR encourages all interested parties to participate in this rulemaking by submitting written comments, views, and data on any or all aspects of this interim final rule. ORR also invites comments that relate to the economic, environmental, or federalism effects that might result from this interim final rule. ORR will review all comments received, but ORR will only post comments that address the topic of the interim final rule. All comments ORR posts to *https://www.regulations.gov* will include any personal or commercial information you provide.

A. Submitting Comments

Comments that will provide the most assistance to ORR will reference a specific portion of the interim final rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. If you submit comments, please indicate the specific section of this document to which each comment applies and provide a reason for each suggestion or recommendation. You may submit your comments and materials online or by email, but please use only one of these means. If you submit a comment online via *https://www.regulations.gov,* it will be considered received when it is received at the Docket Management Facility.

Instructions: To submit your comments online, go to *https://www.regulations.gov* and insert ''XXXX–XXXX–XXXX'' in the ''Search'' box. Click on the ''Comment Now!'' box and input your comment in the text box provided. Click the ''Continue'' box, and if you are satisfied with your comment, follow the prompts to submit it.

For additional information, please read the ''Privacy and Security Notice'' that is available via the link in the footer of *https://www.regulations.gov.*

ORR will consider all comments and materials received during the comment period and may change this rule based on your comments.

B. Viewing Comments and Documents

Docket: To view posted comments, as well as documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov* and insert ''XXXX–XXXX–XXXX'' in the ''Search'' box. Click on the ''Open Docket Folder,'' and you can click on ''View Comment'' or ''View All'' under the ''Comments'' section of the page. Individuals without internet access can make alternate arrangements for viewing comments and documents related to this rulemaking by contacting ORR through the **FOR FURTHER INFORMATION CONTACT** section above. You may sign up for email alerts on the online docket to be notified when comments are posted, or a final rule is published.

C. Privacy Act

As stated in the Submitting Comments section above, please be aware that anyone can search the electronic form of comments received into any dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

II. Table of Abbreviations

ACF—Administration for Children and Families
ALJ—Administrative Law Judge
CAPTA—Child Abuse Prevention and Treatment Act
CWT—ORR's Child Welfare Team
DAB—HHS Departmental Appeals Board
DOJ—U.S. Department of Justice
EIF—Emergency or Influx Facility
FBI—Federal Bureau of Investigation
FSA—Flores Settlement Agreement
HHS—U.S. Department of Health and Human Services