DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Docket No. HRSA-2024-0001

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Office of the Assistant Secretary for Health (OASH) and
Health Resources and Services Administration (HRSA)

Analysis Prepared by
Office of the Assistant Secretary for Planning and Evaluation (ASPE)

Department of Health and Human Services (HHS)

Table of Contents

List of Figures

List of Tables

I. Introduction and Summary

A. Introduction

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. This 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 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 rule with relevant effects over that threshold must also seek input from State, local, and tribal governments.[1] 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.

[1] U.S. Office of Management and Budget, Office of Information and Regulatory Affairs. February 9, 2024. "Report to Congress on the Benefits and Costs of Federal Regulation and Agency Compliance with the Unfunded Mandates Reform Act, FY 2020-2022."

B. Overview of Benefits, Costs, and Transfers

The "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act" final rule removes the current research and institutional review board (IRB) requirements for transplants of kidneys and livers from donors with human immunodeficiency virus (HIV). We have assessed the likely impacts of the final rule, and report in this 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. This 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.

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.

C. Abbreviations, and Acronyms

Table 2 provides a list of abbreviations and acronyms used in this analysis as a reference for readers.

Table 2. List of Abbreviations and Acronyms

Abbreviation or Acronym	Definition
ASPE	Office of the Assistant Secretary for Planning and Evaluation
CPI-U	Consumer Price Index for all urban consumers
DSMB	Data safety monitoring board
ESRD	End-stage renal disease
FRFA	Final regulatory flexibility analysis
HHS	U.S. Department of Health and Human Services
HIV	Human immunodeficiency virus
HOPE Act	HIV Organ Policy Equity Act
HRSA	Health Resources and Services Administration
IRB	Institutional review board
IRFA	Initial regulatory flexibility analysis
KDPI	Kidney donor profile index
MELD	Model for End-Stage Liver Disease
NAICS	North American Industry Classification System
NIH	National Institutes of Health
NPRM	Notice of proposed rulemaking
OASH	Office of the Assistant Secretary for Health
OIRA	Office of Information and Regulatory Affairs
OPO	Organ procurement organization
OPTN	Organ Procurement and Transplantation Network
PELD	Pediatric end-stage liver disease
PLWH	People living with HIV
QALY	Quality-adjusted life year
RFA	Regulatory Flexibility Act
RIA	Regulatory impact analysis
SBA	U.S. Small Business Administration
UMRA	Unfunded Mandates Reform Act
VQALY	Value per quality-adjusted life year
VSL	Value per statistical life
VSLY	Value per statistical life year

D. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

We received one comment that explicitly referenced the findings of the preliminary RIA and several other comments in response to the notice of proposed rulemaking (NPRM) that were relevant to the economic impacts of the proposed rule. We summarize and respond to those comments, grouping similar themes we identified across multiple comment submissions into a single 'comment.' The number assigned to each comment is purely for organizational purposes and does not signify the number of comments received on a particular topic, the value of any particular comment, or the order in which any comment was received or posted. In some instances, we have included citations to one or more specific comments. This practice is intended to provide information for readers seeking additional context and does not signify the value of any particular comment cited or not cited.

(Comment 1) – One comment expressed general support for the findings summarized in the notice of proposed rulemaking and assessed in the preliminary RIA related to Executive Orders 12866, 13563, and 14094, RFA, and UMRA, and noted that the preliminary RIA found that the benefits of proposed rule outweighed the costs.[2]

(Response 1) – We generally agree with the comment. In this RIA, we confirm the findings as they relate to the final rule, including that the benefits of the final rule will outweigh the costs.

(Comment 2) – We received many comments supporting the proposed rule that noted it would increase access to organ transplants, reduce waiting times, and save lives. Several of these comments did not include any particular supporting data or information, while other comments contained references to clinical research and other research, including several studies cited in the NPRM or preliminary RIA. One comment[3] referenced a study published after the NPRM that contributes additional evidence on the safety of kidney transplantation from donors with HIV.[4] Other comments cited research summaries, commentary, or scholarly opinion articles that provide general support for expanded access to transplants for people living with HIV and transplantation of organs from donors with HIV.[5][6][7] At least two comments[8] cited a letter from members of Congress to the HHS Secretary that discusses some of the history of the HOPE Act and that references additional research indicating the potential benefits from increased access to organ transplants from donors with HIV.[9]

---

[2] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0006.
[3] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0048.
[4] Durand, C.M., Massie, A., Florman, S., Liang, T., Rana, M.M., Friedman-Moraco, R., Gilbert, A., Stock, P., Mehta, S.A., Mehta, S. and Stosor, V., 2024. Safety of Kidney Transplantation from Donors with HIV. *New England Journal of Medicine*, 391(15), pp.1390-1401.
[5] Lushniak, S.A. and Durand, C.M., 2022. Donors with human immunodeficiency virus and hepatitis C virus for solid organ transplantation: what's new. *Current Opinion in Infectious Diseases*, 35(4), pp.321-329.
[6] Thornton, J., 2021. Expanding HIV-positive organ donation. *The Lancet*, 397(10270), pp.184-185.
[7] Nambiar, P.H., Doby, B., Tobian, A.A., Segev, D.L. and Durand, C.M., 2021. Increasing the donor pool: organ transplantation from donors with HIV to recipients with HIV. *Annual Review of Medicine*, 72(1), pp.107-118.
[8] Regulations.gov Docket (HRSA-2024-0001). Comment IDs HRSA-2024-0001-0019 and HRSA-2024-0001-0048.
[9] Office of Congresswoman Nikema Williams. Letter dated February 28, 2024. https://d12t4t5x3vyizu.cloudfront.net/nikemawilliams.house.gov/uploads/2024/02/Letter-to-HHS-regarding-HIV-to-HIV-transplants-FINAL-Signed.pdf. Accessed October 31, 2024.

At least ten comments discussed the ongoing organ shortage in relation to the potential benefits of the proposed rule,[10] including comments[11] that noted specific unmet needs for people living with HIV.[12] At least one comment[13] identified a study of individuals with end-stage renal disease that reports differences in the likelihood an individual receives a referral to the kidney transplant waitlist depending on HIV status, with lower referral rates for people living with HIV.[14]

Several comments[15] referenced a study containing recent projections of the number of kidneys and livers potentially available for transplantation from deceased donors with HIV.[16] Several comments[17] also highlighted the potential for the proposed rule to result in additional living donors with HIV, citing a summary of case studies of living kidney donors under the HOPE Act.[18]

Many of these comments discussed the benefits of the proposed rule for people living with HIV. Several comments also noted that the proposed rule would provide additional benefits to people regardless of HIV status. As an example, one commenter noted that the proposed rule "will also increase to utilization of organs from donor with false positive tests for HIV. Doing so is a great step towards improving health equity for individuals with HIV waiting for a transplant and donors living with HIV, as well as increasing the number of available organs for transplant for all those on the waiting list, not just those living with HIV."[19]

(Response 2) – We generally agree with these comments. We note that the preliminary RIA includes these sources of benefits, and we maintain this general approach in this analysis. We have incorporated some of the most relevant studies identified by commenters into the narrative of the analysis and, as discussed in the next section of this RIA, we have incorporated findings from the study containing projections of the number of kidneys and livers potentially available for transplantation from deceased donors with HIV into the estimates of the quantified impacts of the final rule. In response to the comments, we also extend the discussion of the baseline conditions to discuss the organ shortage.

---

[10] Regulations.gov Docket (HRSA-2024-0001). Comment search results for "shortage."
[11] As one example, Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0048.
[12] Mayer, C., Agbobli-Nuwoaty, S.E., Li, J., Carlson, K., Pallela, F.J., Durham, M.D. and Buchacz, K., 2022. Unmet Need for Solid Organ Transplantation among People with HIV and End Stage Kidney or Liver Disease: a Brief Report from the HIV Outpatient Study, 2009-2023. *Journal of Acquired Immune Deficiency Syndromes*, pp.10-1097.
[13] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0047.
[14] Shelton, B.A., MacLennan, P.A., Becker, D.J., Sen, B., Budhwani, H. and Locke, J.E., 2023. Access to the kidney transplant waitlist for people with HIV. *Transplantation*, 107(5), pp.e156-e157.
[15] Regulations.gov Docket (HRSA-2024-0001). Comment IDs HRSA-2024-0001-0027 and HRSA-2024-0001-0044.
[16] Woods, C., Owens, G., Shelton, B.A., MacLennan, P.A., Sawinski, D., Jacobson, J. and Locke, J.E., 2022. Efficacy of hope: Analysis of organ quality and availability among deceased HIV-positive donors. *Transplant Infectious Disease*, 24(6), p.e13916.
[17] Regulations.gov Docket (HRSA-2024-0001). Comment IDs HRSA-2024-0001-0043, HRSA-2024-0001-0044, HRSA-2024-0001-0048, and HRSA-2024-0001-0057.
[18] Durand, C.M., Martinez, N., Neumann, K., Benedict, R.C., Baker, A.W., Wolfe, C.R., Stosor, V., Shetty, A., Dietch, Z.C., Goudy, L. and Callegari, M.A., 2023. Living kidney donors with HIV: experience and outcomes from a case series by the HOPE in Action Consortium. *The Lancet Regional Health–Americas*, 24.
[19] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0042.

(Comment 3) – We received a comment[20] encouraging HHS to emphasize the 'economic benefits' as a rationale for adopting the rule, noting the potential for cost savings from reductions in long-term treatment costs of kidney dialysis and liver disease management. The comment included a supporting reference containing an estimate of cost savings associated with kidney transplantation,[21] and a reference on improved health outcomes for liver transplant recipients living with HIV that does not contain an estimate of cost savings associated with liver transplantation.[22]

(Response 3) – We generally agree with the comment, and note that the preliminary RIA accounted for cost savings from reduced medical expenditures associated with kidney dialysis, and we maintain this general approach when reporting estimates of the costs and cost savings of the final rule in this analysis. Additionally, in response to the comment, we have extended a sensitivity analysis included in the preliminary RIA that applied an alternative estimate of the cost per kidney transplant. In this final RIA, we apply a second alternative estimate based on the study referenced in the comment. However, we did not quantify cost savings from reductions in medical expenditures on liver disease management in the preliminary RIA, and are not aware of comparable studies that would readily enable us to incorporate this potential cost saving impact into the monetary estimates reported in this analysis.

(Comment 4) – We received many comments expressing the view that transplanting organs from donors with HIV is safe. As noted in public comments by the Organ Procurement and Transplantation Network (OPTN):[23] "the OPTN reviewed data safety monitoring board (DSMB) data reports from five years covering more than 300 HOPE Act transplants, and no DSMB identified any patient safety concerns. In addition, as noted in the proposed rule, no reports have been made to the OPTN of safety issues regarding HOPE Act transplants among organ procurement organization (OPO), hospital, or transplant program personnel or in patients, in donor hospitals, or in transplant hospitals." Several other comments cited these OPTN findings. One commenter came to the opposite conclusion, but did not provide any particular supporting data or information.[24]

(Response 4) – We agree with the comments expressing the view that transplanting organs from donors with HIV is safe, and discuss our current assessment of this evidence in greater detail in the preamble of the final rule.

(Comment 5) – We received several comments supporting provisions of the proposed rule that would revise terminology to reference "donors with HIV" or persons "living with HIV." As one example, one comment included the following discussion:[25]

> "We applaud HHS for proposing changes to the regulatory language to reduce stigma surrounding HIV. The shift from terms like 'infected with HIV' to 'living with HIV'

[20] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0022.
[21] Brannon, I. (2023). Saving lives while saving money: The Living Kidney Donor Support Act. *Regulation*, 46(2), 32-37.
[22] Lynch, E.N. and Russo, F.P., 2023. Liver Transplantation in People Living with HIV: Still an Experimental Procedure or Standard of Care? *Life*, 13(10), p.1975.
[23] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0016.
[24] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0038.
[25] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0024.

aligns with the broader effort to combat stigma and discrimination. Stigmatizing language has long contributed to the marginalization of people living with HIV, and updating these terms will reflect a more respectful and inclusive approach.

As advocates, we understand that language plays a critical role in shaping public perception, and we believe that this change will have a positive impact on how HIV is discussed in both healthcare settings and broader societal contexts. We encourage HHS to continue prioritizing the use of respectful, non-stigmatizing language in all future regulations and communications regarding HIV."

Other comments expressed similar themes, that the proposed revisions to terminology "aligns with the principles of dignity and respect long advocated for in the community. Such language shifts are critical to reducing stigma and fostering a more inclusive healthcare environment."[26] Some comments expressed support for addressing instances of stigmatizing language across all HHS programs, including one that noted that broader revisions would ensure "that [people living with HIV] receive respectful, non-stigmatizing care across the healthcare system."[27]

One comment[28] recommended several modifications the proposed regulatory text revising terminology. They suggested adopting "organs from donors with HIV" and similar terminology when specifically referencing kidneys or livers "from donors with HIV," indicating that this terminology is more precise and also less stigmatizing.

(Response 5) – We appreciate the comments, which help us to characterize the some of the benefits associated with revisions to terminology under the final rule. Much of the preliminary RIA, and this final RIA, focuses on impacts that can be monetized, quantified, or potentially quantified, including increases in life expectancy, improvements in quality of life, and time savings; however, we agree with the commenters that these difficult-to-quantify impacts are important and distinct. Thus, we identify these effects as additional sources of unquantified benefits in the Overview of Benefits, Costs, and Transfers and summary Table 1 in Section I.B of this analysis. As discussed in the preamble, we also generally agree with the commenter that recommended several modifications to the proposed regulatory text revising terminology, and have incorporated additional changes into the final rule.

(Comment 6) – We received a comment from OPTN that, among other things, notes that the proposed rule's "stated 15-month timeline for the OPTN to develop, share, and approve policy changes can be accomplished."[29]

(Response 6) – We appreciate the comment. Although this aspect of the comment speaks primarily to the feasibility of the implementation timeline of the proposed rule, it is also relevant to our assessment of the timing of the impacts of the final rule. As discussed in the next section, we have modified the assumptions about the timing of impacts in the preliminary RIA, including to account for the time needed for OPTN to implement the policy.

---

[26] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0005.
[27] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0022. The original text of the comment writes "PLWH" as an abbreviation for "people living with HIV."
[28] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0048.
[29] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0016.

(Comment 7) – We received several comments about the current research and IRB requirements, including comments that suggested revisions to those requirements as they relate to organs other than kidneys and livers. Some comments expressed general principles for revisions, such as to indicate support for "efforts to streamline research requirements for non-liver and kidney HOPE Act transplants while maintaining the appropriate safeguards and allowing for further study,"[30] while other comments were more specific. For example, one comment urged removal of "the requirement that a transplant team perform at least five HIV+ transplants for all HIV+ organs (including heart, lung, and pancreas)," regardless of whether the proposed rule is finalized.[31]

We also received comments that supported removing the research and IRB requirements for kidneys and livers through rulemaking that also expressed support for removing the requirements for other organs "once sufficient evidence of safety and efficacy is available,"[32] or that expressed support for removing the requirements for all organ transplants without conditional or clarifying language.[33] At least one comment[34] supporting removal of the research and IRB requirements for all organ transplants provided a reference to a study that identifies comparable survival rates for heart and lung transplant recipients regardless of HIV status.[35]

(Response 7) – We appreciate the comments. We respond to comments about the current research and IRB requirements and the chosen regulatory action in greater detail in the preamble of the final rule. However, in response to the public comments, we have also extended the analysis of regulatory alternatives in this final RIA to consider and assess a regulatory alternative of lifting the research and IRB requirements for all organs.

E. Summary of Changes

This final RIA makes several changes compared to the preliminary RIA. Throughout the analysis, we update several sources of data, and incorporate information from additional references that help to extend or clarify the narrative. This section documents several of the most significant revisions to the analysis, organized by section of the RIA.

1. Baseline Conditions

In the preliminary RIA, we calibrated our quantitative assessment of the baseline scenario using data on transplants occurring under the HOPE Act covering calendar years 2016 through 2023. In this final RIA, we incorporate an additional partial year of data, covering slightly more than the first three quarters of calendar year 2024. We also extend our quantitative assessment of the baseline scenario to incorporate some of the uncertainty inherent in projecting kidney and liver transplants in the future, even absent any regulatory action. We extend the narrative of this section to briefly note the current organ shortage.

---

[30] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0034.
[31] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0012.
[32] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0024.
[33] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0032.
[34] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0039.
[35] Koval, C.E., Farr, M., Krisl, J., Haidar, G., Pereira, M.R., Shrestha, N., Malinis, M.F., Mueller, N.J., Hannan, M.M., Grossi, P. and Huprikar, S., 2019. Heart or lung transplant outcomes in HIV-infected recipients. *The Journal of Heart and Lung Transplantation*, 38(12), pp.1296-1305.

2. Impacts on Kidney and Liver Transplants

In the preliminary RIA, we adopted projections of the annual number of organs from deceased donors with HIV potentially available for transplant, 192 kidneys and 247 livers, from a study that retrospectively reviewed medical charts from the Philadelphia metropolitan area for deceased patients, estimated probabilities of recovering organs from these patients using donor yield models, and then extrapolated the results to match the U.S. population.[36] From those projections, we made several adjustments to generate a range of estimates for the number of organs transplanted under the proposed rule. In this final RIA, we adopt projections of 200 kidneys and 147 livers from a more recent study that covers a larger patient population and a broader geographic area,[37] and follow a similar procedure to generate a range of estimates for the number of organs transplanted that will be transplanted under the final rule.

We also make two revisions to the quantitative adjustments used to characterize a range of potential outcomes under the final rule. First, in the preliminary RIA, we included an adjustment related to the size of the deceased donor pool to account for potential changes since the data for the prior study were collected. In this final RIA, we no longer make a quantitative adjustment of this nature since our projections come from a study with more recent data. Second, we revise the quantitative adjustment related to consent for organ donation. In the preliminary RIA, we identified a range of estimates based on the findings of two studies and adopted the average, about 72.0%, as our primary estimate of the deceased organ donation consent rate. In this final RIA, we identify a third study[38] and incorporate its findings into the range of estimates, adopting 74.6% as our primary estimate.

We also revise assumptions relating to the timing of the impacts on transplants. In the preliminary RIA, we adopted a four-year phase-in of impacts. Combined with other assumptions about the effective date of a potential final rule, the preliminary RIA reported small increases in the number of transplants beginning in 2025, with the full effects of the final rule occurring in later years. In this final RIA, we adopt a similar approach, but now assume the initial impacts on transplants will begin in 2026. This revised timing assumption incorporates a lag into the impacts on transplants that accounts for the time needed for OPTN to implement the policy and also reflects reduced analytic uncertainty related to the timing of publication and subsequent effective date of a potential future final rule that was present during development of the preliminary RIA.

3. Costs and Cost Savings of the Final Rule

In the preliminary RIA, we adopted estimates of the cost per transplant by organ that did not vary over time. In this final RIA, we incorporate annual real growth rates for these cost estimates to

[36] Richterman, A., Sawinski, D., Reese, P.P., Lee, D.H., Clauss, H., Hasz, R.D., Thomasson, A., Goldberg, D.S., Abt, P.L., Forde, K.A., Bloom, R.D., Doll, S.L., Brady, K.A., and Blumberg, E.A. 2015. An assessment of HIV-infected patients dying in care for deceased organ donation in a United States urban center. *American Journal of Transplantation*, 15(8), pp.2105-2116.

[37] Woods, C., Owens, G., Shelton, B.A., MacLennan, P.A., Sawinski, D., Jacobson, J. and Locke, J.E., 2022. Efficacy of hope: Analysis of organ quality and availability among deceased HIV-positive donors. *Transplant Infectious Disease*, 24(6), p.e13916.

[38] Nguyen, A.Q., Anjum, S.K., Halpern, S.E., Kumar, K., Rasmussen, S.E.V.P., Doby, B., Shaffer, A.A., Massie, A.B., Tobian, A.A., Segev, D.L. and Sugarman, J., 2018. Willingness to donate organs among people living with HIV. *Journal of Acquired Immune Deficiency Syndromes*, 79(1), pp.e30-e36.

account for observed increases over time in the inflation-adjusted costs associated with transplantation.

4. Analysis of Regulatory Alternatives to the Final Rule

In the preliminary RIA, we assessed an alternative to the proposed rule of implementing the general policy approach of lifting the research requirement sooner, i.e., faster than a typical timeline for regulatory actions implemented through notice-and-comment rulemaking. To assess the benefits and costs of that alternative, we assumed that the impacts would begin 6 months earlier than the estimates of the proposed rule and operationalized this difference through discounting. We have removed this alternative from this final RIA, as it is no longer relevant at the time of final action on this rulemaking.

In response to public comment, we extend the analysis of regulatory alternatives to assess an additional regulatory alternative of lifting the research and IRB requirements for all organs.

5. Uncertainty and Sensitivity Analysis

We update the Monte Carlo simulation to incorporate uncertainty in the baseline scenario, and to update several of the parameters.

In the preliminary RIA, we based our primary estimates of the transplants that would occur under the proposed rule on a study that reported projections of the annual number of kidneys and livers from deceased donors with HIV potentially available for transplant, and performed a sensitivity analysis based on projections reported in another study. In this final RIA, we extend this sensitivity analysis to consider four sets of projections from three studies as well as the primary estimates reported in the preliminary RIA for comparison. We also extend a sensitivity analysis appearing in the preliminary RIA that considered an alternative estimate of the cost per kidney transplant to also consider a second estimate.

6. Final Regulatory Flexibility Analysis

We reviewed the sources of data referenced in the initial regulatory flexibility analysis, updated these sources when newer data were available, and updated all estimates to match revisions described in other sections of the RIA. We also extended the analysis to consider the beneficial economic impacts of the final rule on small entities.

II. **Final Economic Analysis of Impacts**

A. Background

The HIV Organ Policy Equity Act (HOPE) Act, enacted on November 21, 2013, removed a prior restriction on organ transplantation from donors with HIV so that such transplants could be evaluated in a research setting. The HOPE Act prescribed that organ transplantation from donors with HIV could be carried out for individuals living with HIV prior to organ transplantation and who are participating in clinical research approved by an institutional review board under specified research criteria. HRSA published a final rule to implement the HOPE Act on May 8, 2015.[39] Under those regulations, organs from donors without HIV may be transplanted to recipients regardless of HIV status, while organs from donors with HIV may be transplanted to recipients living with HIV only in a research setting, and may not be transplanted to recipients without HIV. On September 12, 2024, HHS published a notice of proposed rulemaking (NPRM) to remove the research and IRB requirements for transplants of kidneys and livers from donors with HIV[40] and published a corresponding preliminary regulatory impact analysis (RIA).[41] HHS requested public comments on the proposed rule and the preliminary RIA. After considering the public comments, HHS is publishing a final rule removing the research and IRB requirements for transplants of kidneys and livers from donors with HIV.

B. Analytic Approach

In conducting this analysis, we began by identifying the most consequential impacts that will likely occur under the final rule and the regulatory alternatives we assess. For the final rule, these impacts relate to the incremental effects on the number of kidney and liver transplants performed annually. To assess benefits, we quantify increases in life expectancy for both kidney and liver transplant recipients and monetize these effects using a value per statistical life year. For kidney transplant recipients, we quantify improvements in health-related quality-of life, measured as a change in health utility occurring prior to the impacts on life expectancy, and monetize these effects using a value per quality-adjusted life year. We also quantify time savings for kidney transplant recipients from fewer kidney dialysis visits and monetize these effects using a value of time. To assess costs, we estimate the change in medical expenditures associated with additional transplants. For kidney transplants, we identify a mostly offsetting cost-saving impact from reduced expenditures on kidney dialysis. We report the net impact on medical expenditures as the costs of the final rule, and separately report the cost savings as distributional impacts, as they represent a transfer of monetary payments that will go to entities providing medical care associated with kidney dialysis to entities providing medical care associated with kidney transplantation. We quantify the time spent by transplant centers to read and understand the final rule, to review policies and procedures, and to train staff, and monetize these impacts using estimates of the value of time that vary by occupation. We identify other sources of quantified

[39] Health Resources and Services Administration. May 8, 2015. "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act" final rule. Federal Register. 80 FR 26464.
[40] Office of the Assistant Secretary for Health and Health Resources and Services Administration. September 12, 2024. "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act" notice of proposed rulemaking. Federal Register. 89 FR 74174.
[41] Office of the Assistant Secretary for Planning and Evaluation. September 12, 2024. "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act" Preliminary Regulatory Impact Analysis. Regulations.gov Docket (HRSA-2024-0001). Document ID HRSA-2024-0001-0001.

but not monetized impacts, and discuss other non-quantified impacts. For one regulatory alternative, we also assess the incremental effects on heart, lung, and pancreas transplants, and the associated economic impacts of those transplants. To reduce the complexity of the analysis of the final rule and regulatory alternatives, we adopt a simplifying modeling assumption that each transplant recipient receives a single organ, although multi-organ transplants occur in practice.

For the purposes of this analysis, we assume that the final rule will begin to take effect in 2025 and that the initial impacts on transplants will begin in 2026. We model several important sources of uncertainty with our quantified impact estimates, including uncertainty in the number of transplants that will occur under the baseline, several factors that could affect the number of kidneys and livers that will be transplanted under the final rule including consent for organ donation and transplants from living donors, and also uncertainty about when the effects of the final rule will fully materialize. When quantifying the impacts of transplants on morbidity, we model uncertainty in the average health-related quality-of-life improvements for kidney transplant recipients. When monetizing the health benefits attributable to the final rule, we model uncertainty in the population-average estimates of the value per statistical life, value per statistical life year, and value per quality-adjusted life year. To simplify the narrative, we report most intermediate calculations using our primary estimates, and present a range of estimates in a Monte Carlo simulation that serves as a formal quantitative analysis of some of the relevant uncertainties about the impacts of the final rule. We consider other sources of uncertainty throughout the analysis, and report the findings of several additional sensitivity analyses.

In general, we report rounded total benefit, cost, and transfer estimates, but have not rounded several of the underlying inputs and intermediate calculations for transparency and reproducibility of the estimation process. The unrounded inputs and intermediate calculations should not be interpreted as representing a particular degree of precision. Unless otherwise noted, all monetary estimates are reported in constant 2023 dollars: when necessary, we adjust estimates from other years using annual averages of the Consumer Price Index for all Urban Consumers (CPI-U).[42]

C. Baseline Conditions

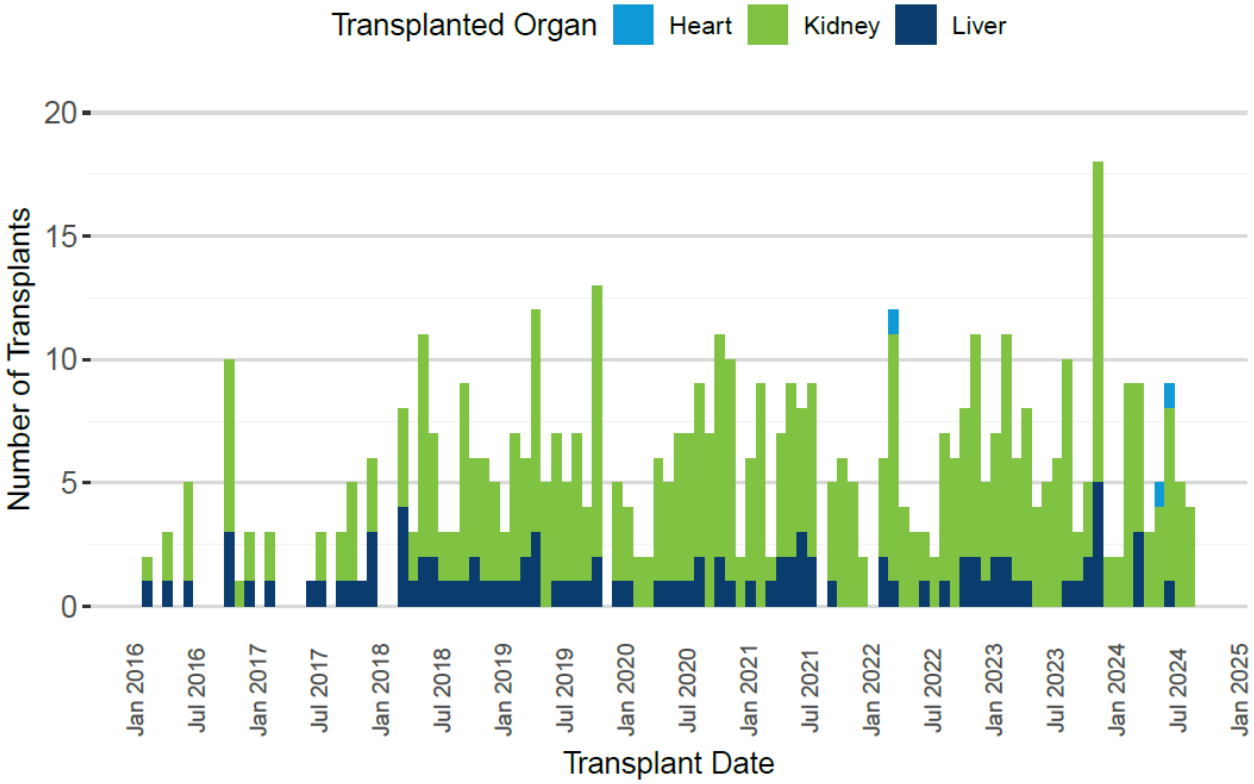
The Organ Procurement and Transplantation Network (OPTN) membership directory lists 248 transplant centers with active member status.[43] Among these, 142 centers have both kidney and liver transplant programs; 91 centers have a kidney program but not a liver program; 1 center has a liver program but not a kidney program; and 13 centers have at least one organ program but no programs for kidneys or livers. There are 55 kidney, liver and heart programs (48 deceased donor and 7 living donor) among 28 centers with Hope Act IRB approval.[44]

As of October 4, 2024, 519 organs have been transplanted between donors with HIV and patients with HIV, all occurring under the requirements of the 2015 HOPE Act final rule and additional

[42] U.S. Bureau of Labor Statistics. CPI for all Urban Consumers (CPI-U), Not Seasonally Adjusted, https://data.bls.gov/timeseries/CUUR0000SA0.
[43] Organ Procurement and Transplantation Network. "Search Membership." https://optn.transplant.hrsa.gov/about/search-membership/. Accessed October 31, 2024.
[44] These counts correspond to October 4, 2024. A similar list corresponding to an earlier time period can be found online. Organ Procurement and Transplantation Network. May 31, 2024. "HOPE Act participating hospitals." https://optn.transplant.hrsa.gov/media/ex3bmasx/hope-act-hospitals.pdf.

research criteria published separately.[45] Over this time period, these transplants include 419 kidneys, 97 livers, 3 hearts, and no other organs. Figure 1 presents the monthly counts of kidney, liver, and heart transplant recipients between January 1, 2016 and October 4, 2024.

Figure 1. Monthly Transplants Performed Under the HOPE Act



To project baseline transplants over the time horizon of the analysis, we adopt as our primary estimate the annual averages of kidney and liver transplant recipients between January 1, 2016 and October 4, 2024. Over this period, we observe 348 kidney transplants (including 3 living donors) and 66 liver transplants, for an average of 60.5 kidney transplants and 11.5 liver transplants per year. We account for uncertainty in our baseline scenario by adopting a range of estimates derived from the sample means (60.4 and 11.5) and standard errors of the mean observed annual transplants (2.81 and 1.48). When calculating standard errors, we adopt analytic weights that assign full weight to the complete years of data, corresponding to 2019 through 2023, and partial weight to the data for 2024.[46] We depict our baseline projections of kidney transplants in Figure 2 and for liver transplants in Figure 3, both located in the next section.

Data from OPTN for October 31, 2024 indicates there are 104,571 candidates waiting for organ transplants, including 90,290 candidates waiting for kidneys and 9,402 candidates waiting for

[45] National Institutes of Health. November 25, 2015. "Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV," notice. Federal Register. 80 FR 73785.

[46] Specifically, we adopt analytic weight of 1 for the years with full data; for 2024, an analytic weight of $0.76 \approx 278/366$, where October 4, 2024 is the 278th day of calendar year 2024, which is a leap year.

livers.[47] Every 8 minutes another person is added to the waiting list, and nearly 17 people die every day while waiting for a transplant.[48] This organ shortage indicates the potential for policies that increase the number of kidneys and livers available for transplantation to generate substantial health benefits to individuals who would otherwise die waiting for a transplant under the baseline scenario. This unmet need for organ transplantation for has also been documented for people living with HIV.[49]

D. Impacts on Transplants

Most of the quantified and monetized impacts reported in this analysis are connected to the incremental effect of the final rule on the number of kidney and liver transplants performed annually. Our approach to estimating these impacts begins with projections of the annual number of donor organs from deceased donors with HIV potentially available for transplantation. We make several adjustments to these projections relating to consent for organ donation and transplants from living donors. To compute the impacts on kidney and liver transplants attributable to the final rule, we subtract our estimates of number of transplants occurring under our baseline scenario. We account for several sources of uncertainty by adopting a range of estimates for the adjustments, a range of estimates of transplants occurring under the baseline scenario, and a range of possible timelines for when the impacts of the final rule will fully materialize. To simplify the narrative of this section, we present tables that contain primary estimates, while documenting the full range of estimates that are used in the Monte Carlo simulation in Section II.H used to estimate the range of total benefit and cost estimates reported in Table 1 and the summary.

1. Organs from Deceased Donors

We have identified three studies relevant to estimating the number of organs from deceased donors with HIV potentially available for transplantation under the final rule.

First, Boyarsky et al. (2011) analyzed a range of data sources and reported a range of potential deceased donors "with well-controlled HIV and causes of death ordinarily compatible with organ donation."[50] Using Nationwide Inpatient Sample data, they identified 534 annual deceased donors with HIV, and estimated that they represent 63 kidney-only donors, 221 liver-only donors, and 250 kidney and liver donors. This study did not separately report estimates of the number of kidneys or livers that would be available. For more direct comparability with the other two studies, we adopt an assumption that each deceased kidney donor yields an average of 1.39

[47] Organ Procurement and Transplantation Network. Data. Waiting list candidates as of 10/31/2024. https://optn.transplant.hrsa.gov/data/.
[48] Health Resources and Services Administration. Organ Donation Statistics. September 2024. https://www.organdonor.gov/learn/organ-donation-statistics.
[49] Mayer, C., Agbobli-Nuwoaty, S.E., Li, J., Carlson, K., Pallela, F.J., Durham, M.D. and Buchacz, K., 2022. Unmet Need for Solid Organ Transplantation among People with HIV and End Stage Kidney or Liver Disease: a Brief Report from the HIV Outpatient Study, 2009-2023. *Journal of Acquired Immune Deficiency Syndromes*, pp.10-1097.
[50] Boyarsky, B.J., Hall, E.C., Singer, A.L., Montgomery, R.A., Gebo, K.A. and Segev, D.L., 2011. Estimating the potential pool of HIV-infected deceased organ donors in the United States. *American Journal of Transplantation*, 11(6), pp.1209-1217. Quote from page 1210.

recovered kidneys[51] and that each deceased liver donor yields an average of 1 recovered liver. With this additional assumption, we interpret these findings from study to indicate that 435 kidneys and 471 livers would be potentially available for transplantation.

Second, Richterman et al. (2015) retrospectively reviewed medical charts from the Philadelphia metropolitan area for deceased patients who had HIV, estimated probabilities of recovering organs from these patients using donor yield models, and then extrapolated the results to match the U.S. population.[52] Based on the experience of this metropolitan area, from which the estimate was four to five new deceased donors annually, the study estimated that 192 kidneys and 247 livers would be potentially available for transplantation.

Third, Woods et al. (2022) discusses the other studies, including that Boyarsky et al. (2011) "did not exclude donors with comorbidities that preclude donation and did not examine viral load," and that Richterman et al. (2015) "was limited to deaths in Philadelphia, which may limit the generalizability."[53] They analyze data from "a national longitudinal cohort study of [people living with HIV] to identify potential deceased donors across the United States and characterize both organ quality and viral control," potentially addressing some of the limitations of the two earlier studies.[54] They estimate 792 kidneys and 433 livers potentially available for transplantation annually, and also report a subset of 200 kidneys and 147 livers from lower-risk donors based on viral load and kidney donor profile index (KDPI) score. An OPTN guide for clinicians notes that the KDPI "combines a variety of donor factors into a single number that summarizes the likelihood of graft failure after deceased donor kidney transplant," and predicts "how long a deceased donor kidney is expected to function relative to all of the kidneys recovered in the U.S. during the last year."[55]

In our main analysis, we adopt annual projections of organs potentially available for transplants of 200 kidneys and 147 livers, corresponding to estimated counts of lower-risk organs reported in Woods et al. (2022). In a supplementary sensitivity analysis reported in Section II.H, we report the annual impacts of the final rule that considers a range of scenarios for organs from deceased donors that are based on estimates from Boyarsky et al. (2011), Richterman et al. (2015), higher estimates reported in Woods et al. (2022), and our primary estimates reported in the preliminary RIA for comparison. This sensitivity analysis adopts a common baseline scenario discussed in Section II.C and other assumptions discussed in this section.

---

[51] Estimate for 2022 from Israni, A.K., Zaun, D.A., Gauntt, K., Schaffhausen, C.R., Lozano, C., McKinney, W.T., Miller, J.M. and Snyder, J.J., 2024. OPTN/SRTR 2022 Annual Data Report: Deceased Organ Donation. *American Journal of Transplantation*, 24(2), pp.S457-488.

[52] Richterman, A., Sawinski, D., Reese, P.P., Lee, D.H., Clauss, H., Hasz, R.D., Thomasson, A., Goldberg, D.S., Abt, P.L., Forde, K.A., Bloom, R.D., Doll, S.L., Brady, K.A., and Blumberg, E.A. 2015. An assessment of HIV-infected patients dying in care for deceased organ donation in a United States urban center. *American Journal of Transplantation*, 15(8), pp.2105-2116.

[53] Woods, C., Owens, G., Shelton, B.A., MacLennan, P.A., Sawinski, D., Jacobson, J. and Locke, J.E., 2022. Efficacy of hope: Analysis of organ quality and availability among deceased HIV-positive donors. *Transplant Infectious Disease*, 24(6), p.e13916. Quotes from page 3.

[54] The original authors write "PWH" as an abbreviation for "people with HIV."

[55] Organ Procurement and Transplantation Network. "Kidney Donor Profile Index (KDPI) Guide for Clinicians" https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/.

2. Consent for Organ Donation

The projections of kidneys and livers potentially available for transplantation from deceased donors described above do not account for authorizations necessary prior to organ donation. Thus, all else equal, adopting these counts without adjusting for a share of potential donor organs that are not transplanted due to a lack of consent by the deceased donor or surviving family member or guardian would introduce upward bias into our estimates of the number of kidney and liver transplants that will occur under the final rule.

We identify three studies that inform our range of estimates for the deceased organ donation consent rate. For our central estimate, we adopt findings of study that "overall 75% of potential donors are estimated to consent annually,"[56] drawing from self-reported consent rate data from organ procurement organizations. For our lower-bound estimate, we adopt the findings of a second study that reports a lower share, 68.9%, calculated using potential donor-level data.[57] For our upper-bound estimate, we adopt findings of a third study that surveyed individuals living with HIV that reported 79.8% were willing to be a deceased donor.[58] When modeling the distribution of possible values of this parameter, we adopt a triangle distribution with range [0.689,0.798] and mode 0.750, and a primary estimate of 0.746, corresponding to the mean of the triangle distribution. As an example of how this multiplier and other multipliers are incorporated into this analysis, applying the primary estimate of the deceased organ donation consent rate of 74.6% reduces the estimate from 200 kidneys potentially available for transplant to 149 kidneys for which consent is also obtained.

3. Transplants from Living Donors

The projections reported above correspond to studies estimating organs potentially available for transplantation from deceased donors with HIV. We also considered the extent to which the final rule will result in additional transplants from living donors. Since 2019, about 31% of all kidney donors (inclusive of all donors regardless of HIV status) are living donors; for livers, this share is about 5%.[59] If the ratio of transplants from living donors to deceased donors extends to the change in organs anticipated under the final rule, this would increase the total transplants by about 33% for kidneys and 6% for livers compared to an assumption of no additional live donors. Underlying this calculation is an additional assumption that 1.39 kidneys are recovered and transplanted per deceased kidney donor,[60] with 1 kidney per living donor, and 1 liver transplant per living or decreased live donor. To account for uncertainty in the number of transplanted organs from living donors, we adopt quantitative adjustments specific to each organ.

---

[56] Siminoff, L.A., Agyemang, A.A. and Traino, H.M., 2013. Consent to organ donation: a review. *Progress in Transplantation*, 23(1), pp.99-104.

[57] Goldberg, D.S., Halpern, S.D. and Reese, P.P., 2013. Deceased organ donation consent rates among racial and ethnic minorities and older potential donors. *Critical Care Medicine*, 41(2), p.496.

[58] Nguyen, A.Q., Anjum, S.K., Halpern, S.E., Kumar, K., Rasmussen, S.E.V.P., Doby, B., Shaffer, A.A., Massie, A.B., Tobian, A.A., Segev, D.L. and Sugarman, J., 2018. Willingness to donate organs among people living with HIV. *Journal of Acquired Immune Deficiency Syndromes*, 79(1), pp.e30-e36.

[59] Health Resources and Services Administration. Organ Donation and Transplantation. Analysis of data from January 1, 2019 through March 31, 2024. https://data.hrsa.gov/topics/health-systems/organ-donation.

[60] Estimate for 2022 from Israni, A.K., Zaun, D.A., Gauntt, K., Schaffhausen, C.R., Lozano, C., McKinney, W.T., Miller, J.M. and Snyder, J.J., 2024. OPTN/SRTR 2022 Annual Data Report: Deceased Organ Donation. *American Journal of Transplantation*, 24(2), pp.S457-488.

For both organs, we adopt a lower-bound multiplier of 1, corresponding to no additional transplanted organs from living donors with HIV beyond the transplants occurring under the baseline scenario. For kidneys, we adopt an upper-bound multiplier of 1.33; and for livers, we adopt an upper-bound multiplier of 1.06. These upper-bound multipliers are consistent with a scenario of the current ratio of transplants from living donors to deceased donors extends to the change in organ transplants anticipated under the final rule. For kidneys, we identify a central estimate of about 1.01,[61] corresponding to the additional kidney transplants from living donors occurring under the research and IRB requirements of the 2015 HOPE Act final rule.[62] Under the research and IRB requirements, no liver transplants from living donors with HIV have occurred as of October 4, 2024, so we adopt a central estimate of 1. When modeling this range for this multiplier for kidneys, we adopt a triangle distribution with range [1, 1.33] and mode 1.01; for livers, we adopt a triangle distribution with a range of [1, 1.06] and mode 1. For our primary estimates, we adopt multipliers using the mean of each triangle distribution: 1.11 for kidneys, and 1.02 for livers.

We considered modeling changes in the size of the living donor pool throughout the time horizon of our analysis, which begins in 2025. Potentially relevant factors for this projection include the size of the U.S. population, which is generally increasing, and HIV incidence, which is generally decreasing.[63] Ultimately, this analysis does not make further adjustments to account for the potential change over time in the size of the live donor pool.

4. False-Positive Donors

In addition to increasing the number of kidneys and livers transplanted from donors with HIV, the final rule could result in additional organs donated from donors without HIV. As described in one study, "the HOPE Act has also facilitated the allocation of organs from donors with suspected false-positive HIV tests, that is potential donors who have no known history of HIV but have unanticipated, discordant HIV screening tests."[64] The authors note that organs from this pool of potential donors were generally discarded prior to the HOPE Act to avoid HIV transmission risks. They document several cases where additional testing confirmed that unanticipated results from screening tests represented false-positive results. Based on typical false-positive rates for screening assays, the authors estimate there might be 50-100 HIV false-positive donors per year. Expanded organ transplants from donors with HIV under the final rule could result in additional impacts associated with additional testing for suspected HIV false-positive donors and thus additional organ donations from donors without HIV; however, we have not adjusted our estimates or otherwise quantified this potential impact.

---

[61] As of October 4, 2024, among 419 kidney transplants, 3 were from living donors. 419/416 ≈ 1.01.

[62] Durand, C.M., Martinez, N., Neumann, K., Benedict, R.C., Baker, A.W., Wolfe, C.R., Stosor, V., Shetty, A., Dietch, Z.C., Goudy, L. and Callegari, M.A., 2023. Living kidney donors with HIV: experience and outcomes from a case series by the HOPE in Action Consortium. *The Lancet Regional Health–Americas*, 24.

[63] HIV.gov. August 15, 2024. "U.S. Statistics." https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/.

[64] Durand, C.M., Halpern, S.E., Bowring, M.G., Bismut, G.A., Kusemiju, O.T., Doby, B., Fernandez, R.E., Kirby, C.S., Ostrander, D., Stock, P.G., Mehta, S., Turgeon, N.A., Wojciechowski, D., Huprikar, S., Florman, S., Ottmann, S., Desai, N.M., Cameron, A., Massie, A.B., Tobian, A.A.R., Redd, A.D., Segev, D.L. (2018). Organs from deceased donors with false-positive HIV screening tests: An unexpected benefit of the HOPE act. American Journal of *Transplantation*, 18(10), 2579–2586. https://doi.org/10.1111/ajt.14993.

5. Impacts on Kidney and Liver Transplants

Combining the initial estimates with the full range of multipliers, we compute a full range of 138 to 212 kidneys transplanted annually under the final rule, with a primary estimate of 166; and a range of 101 to 124 livers transplanted annually, with a primary estimate of 112.[65] To compute the impacts on kidney and liver transplants attributable to the final rule, we subtract our estimates of number of transplants occurring under our baseline scenario, about 60 kidneys and 11 livers. For our primary estimates, we anticipate an increase of about 105 kidney transplants and 100 liver transplants annually.[66]

6. Timing of Impacts on Transplants

The above estimates correspond to the number of kidneys and livers transplanted when the impacts of the final rule fully materialize. This is unlikely to occur in the first year under the final rule. We adopt an implementation timeline that is informed by the experience of the HOPE Act and 2015 final rule. We adopt a central estimate of 4 years, which corresponds to the number of years between publication of the 2015 final rule and 2019, when the total number of transplanted organs (74) first met or exceeded the primary estimates of our baseline scenario. We assume that the impacts of the final rule are phased in linearly, such that for a 4-year implementation timeline, 25% of the impacts on transplants occur in the first year, 50% occur in the second year, 75% occur in the third year, and 100% of occur in the fourth year and subsequent years. We assume that the 4-year phase in of effects will begin in 2026, which accounts for the time for OPTN to develop, share, and approve policy changes. To account for uncertainty in the time until the full realization of impacts, we adopt a range of estimates for the yearly phase-in of effects, with a lower-bound implementation timeline of 3 years and an upper-bound implementation timeline of 6-years. When modeling this parameter, we adopt a uniform distribution for the annual phase in of impacts with range [1/6,1/3]. This distribution produces a sequence of average yearly estimates of the phase-in of impacts for the 10 years of the time horizon of our analysis, beginning in 2025, of {0, 1/4, 1/2, 3/4, 11/12, 59/60, 1, 1, 1, 1}. As one example calculation used to produce this sequence, in the fourth year, our primary estimate is 3/4, which is the average between 1/2, corresponding to the third year of a 6-year phase-in period, and 1, corresponding to the third year of a 3-year phase-in period. Figure 2 and Figure 3 depict ranges of kidney and liver transplants occurring in each year under the baseline scenario, and for a range of outcomes under the final rule. For these figures, the shaded areas correspond to 90% confidence intervals of the projected transplants from the simulation reported in Section II.H.

[65] These ranges correspond to minimum and maximum estimates. Elsewhere, including Table 1 and the summary, when reporting primary, low, and high estimates, we adopt the mean, 5th percentile, and 95th percentile of the outcomes of a Monte Carlo simulation.

[66] The impacts on transplants are rounded to the nearest whole number, but calculated using unrounded estimates.

Figure 2. Annual Kidney Transplants: Baseline and Final Rule Scenarios

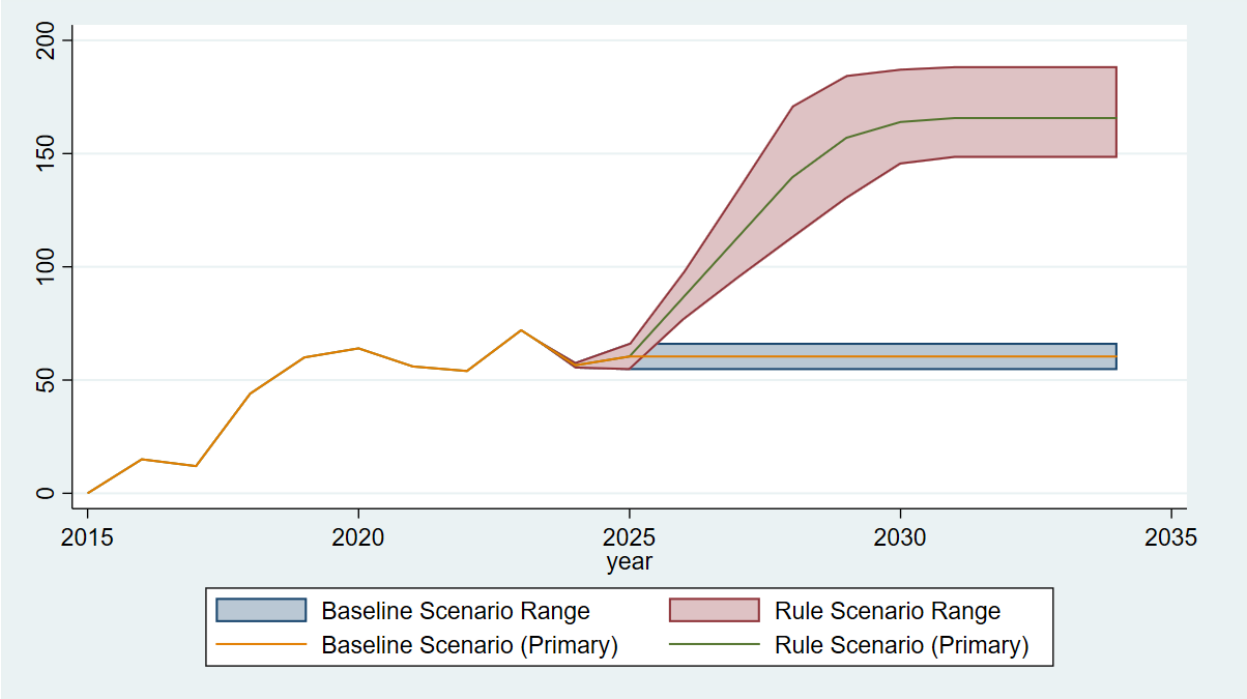


Figure 3. Annual Liver Transplants: Baseline and Final Rule Scenarios

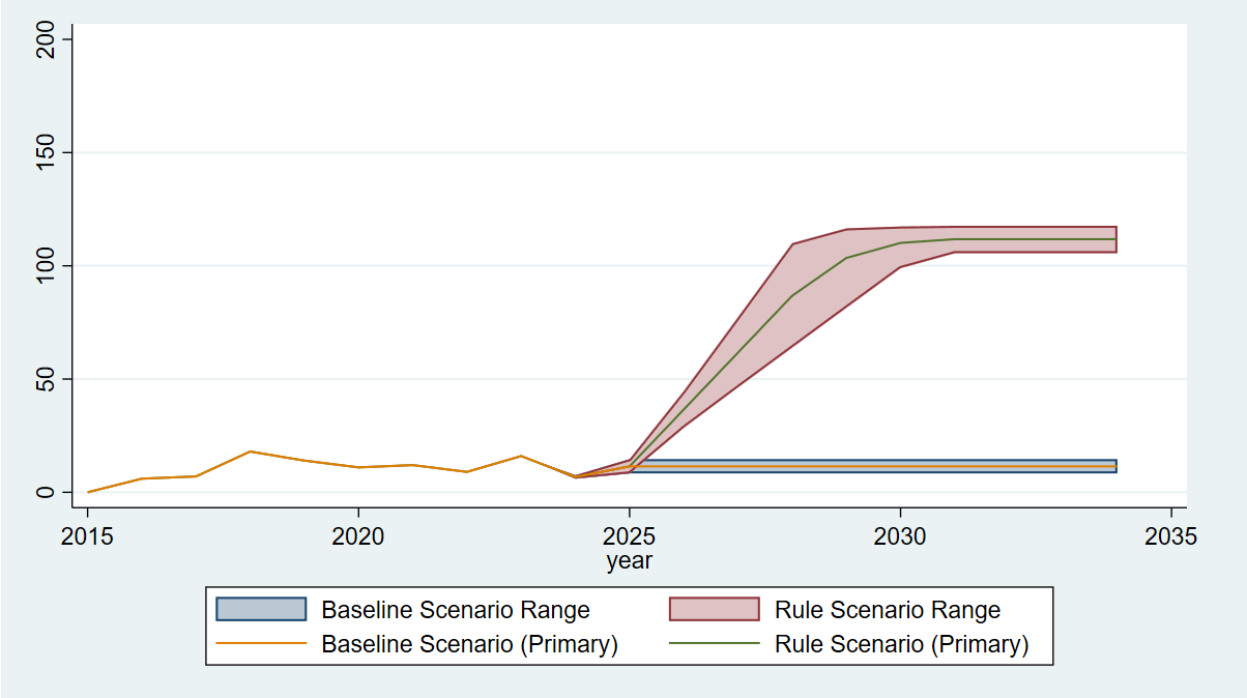


Table 3 reports the number of kidneys and livers transplanted under the baseline, under the final rule, and the impacts attributable to the final rule. Figure 4 and Figure 5 present the impacts on kidney and liver transplants. For these figures, the shaded areas correspond to a 90% confidence interval of the projected impacts from the simulation reported in Section II.H.

Table 3. Impacts on Kidney and Liver Transplants

Year	Baseline		Final Rule		Impact	
	Kidney	Liver	Kidney	Liver	Kidney	Liver
2025	60	11	60	11	0	0
2026	60	11	87	37	26	25
2027	60	11	113	62	53	50
2028	60	11	139	87	79	75
2029	60	11	157	103	97	92
2030	60	11	164	110	104	99
2031	60	11	166	112	105	100
2032	60	11	166	112	105	100
2033	60	11	166	112	105	100
2034	60	11	166	112	105	100

Note: impacts on transplants rounded to the nearest whole number, but calculated using unrounded estimates.

Figure 4. Annual Impacts of the Final Rule on Kidney Transplants

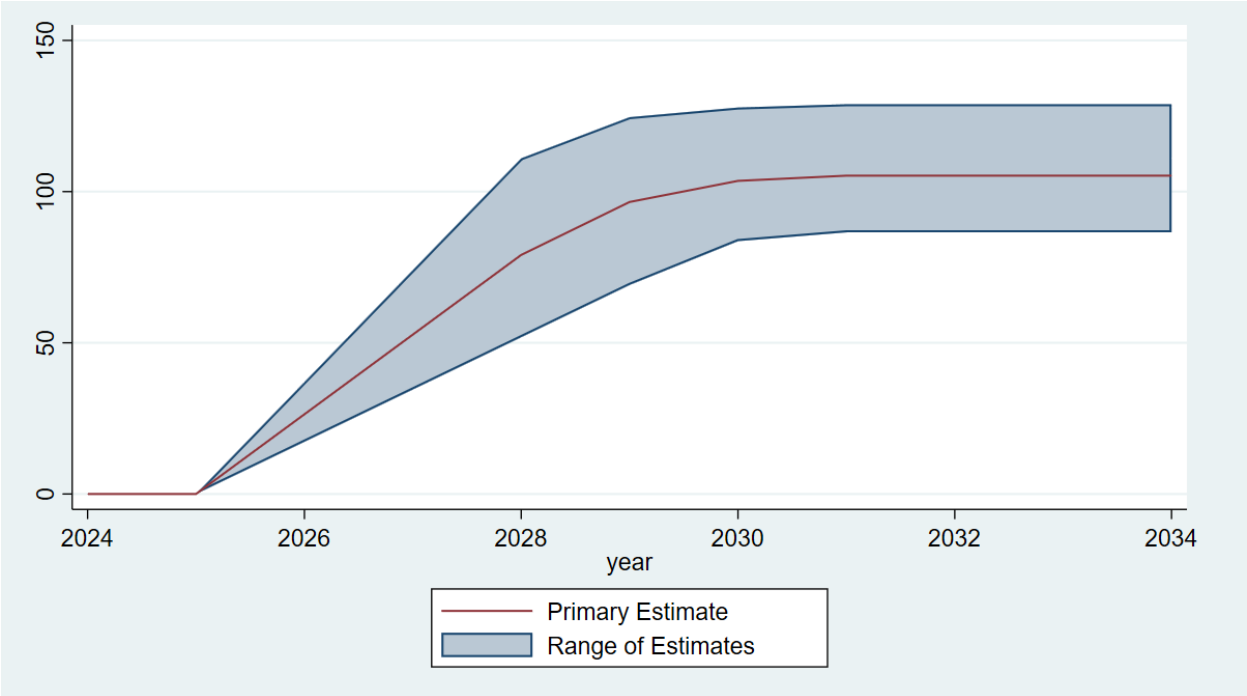
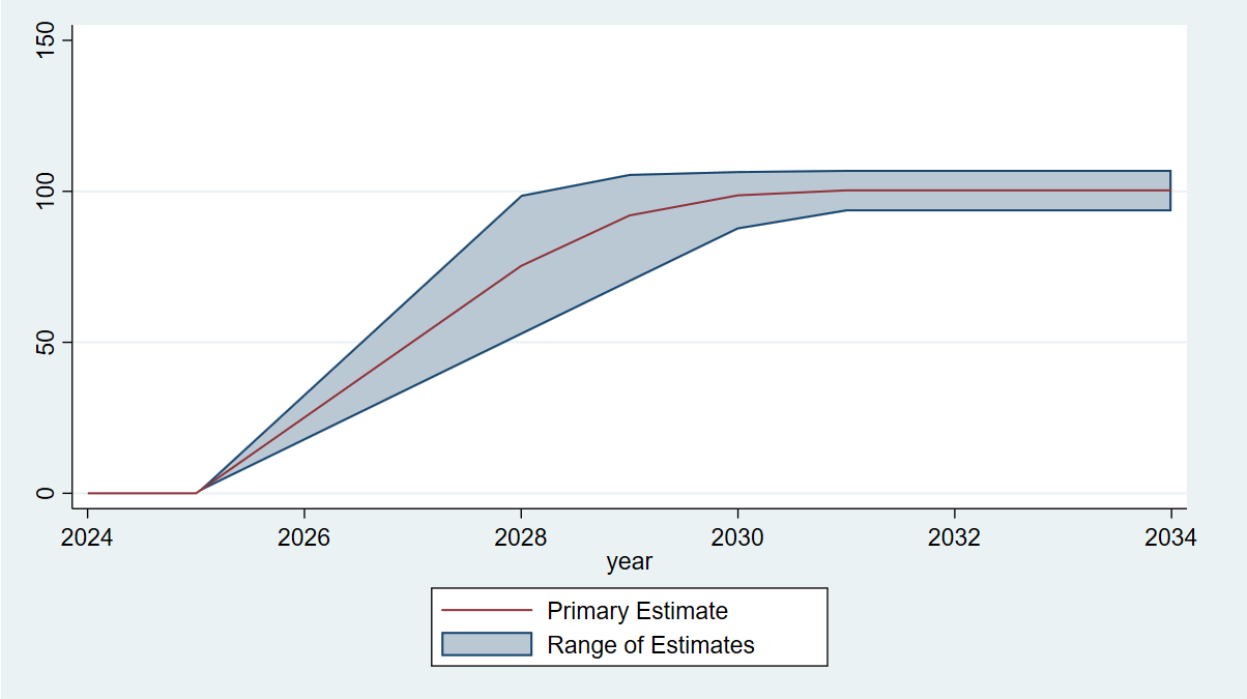


Figure 5. Annual Impacts of the Final Rule on Liver Transplants



To put these impacts into perspective, in 2023, 27,318 kidney transplants and 10,521 liver transplants were carried out from both living and deceased donors.[67] When the effects of the final rule fully materialize, the additional 105 kidney and 100 liver transplants will represent an increase in the total number of kidney transplants by about 0.4% and an increase in the total number of liver transplants by about 0.9%.

E. Benefits of the Final Rule

This section summarizes the findings of research on the health benefits of transplantation. We highlight several findings related to transplantation for the general population and evidence specific to recipients with HIV, including evidence from clinical trials and other research performed under the HOPE Act. We also describe our approach to quantifying and monetizing the health benefits associated with kidney and liver transplants and time-saving benefits associated with fewer kidney dialysis treatments. These quantified benefits will primarily be realized by transplant recipients living with HIV receiving organs from donors with HIV as a direct result of the final rule. For individuals living with HIV, enrollment in a HOPE Act trial registry for kidneys is associated with higher transplant rates, shorter wait times, and lower cumulative incidence of death than for individuals not enrolling.[68] Benefits will, in some cases, also be experienced by recipients (living with or without HIV) receiving organs from donors without HIV through reduced waiting times.

[67] Health Resources and Services Administration. Organ Donation and Transplantation. https://data.hrsa.gov/topics/health-systems/organ-donation.

[68] Motter, J.D., Hussain, S., Brown, D.M., Florman, S., Rana, M.M., Friedman-Moraco, R., Gilbert, A.J., Stock, P., Mehta, S., Mehta, S.A., Stosor, V., et al. 2023. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. *Transplantation*, pp.10-1097.

We note that the estimates in this section represent averages across patients who vary widely in age, medical condition, life expectancy, and type of organ failure. For example, some transplant recipients may have low life expectancies without transplant and would stand to gain the most years of life from a transplant; however, these same patients, on average, tend to have slightly lower survival rates post-transplant. There are additional complexities that we have not incorporated into the estimates, such as the ability of kidney transplant recipients to return to dialysis if a transplanted kidney fails, leading to both additional costs and additional benefits. Similarly, we adopt a simplifying modeling assumption that each transplant recipient receives a single organ, although multi-organ transplants occur in practice.

1. Research on the Health Benefits of Transplantation

Organ transplantation significantly extends lives. There is extensive literature on life expectancy before and after transplant, quality of life, and cost savings for transplant recipients. One literature review covering 1968 to 2007 found essentially universal agreement that kidney transplants were substantially life-extending and also cost-reducing.[69] The authors concluded that "[r]enal transplantation… is the most beneficial treatment option for patients with end-stage renal disease and is highly cost-effective compared to no therapy. In comparison to dialysis, renal transplantation has been found to reduce costs by nontrivial amounts while improving health both in terms of the number of years of life and the quality of those years of life." More recent studies and other syntheses have reached similar conclusions. For example, in one article, authors reviewed 110 studies and concluded that the vast majority of kidney transplant recipients showed major improvement in life quality and reductions in mortality compared to those remaining on dialysis.[70]

Various studies have confirmed that transplant candidates with HIV, at a population level, experience significant benefits from kidney and liver transplantation. For example, as discussed in greater detail in the preamble of the final rule, the National Institutes of Health (NIH) has funded several studies that specifically evaluate HOPE Act kidney transplants and liver transplants. These NIH-funded studies include a multicenter pilot study launched in 2016 to determine safety and efficacy of HOPE Act kidney transplants that 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.[71] These NIH-funded studies also include a pilot study that 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

[69] Huang, E., Thakur, N., and Meltzer, D. 2008. "The Cost-Effectiveness of Renal Transplantation," When Altruism Isn't Enough, edited by Sally Satel. AEI Press. https://www.aei.org/wp-content/uploads/2014/07/-when-altruism-isnt-enough_161836373082.pdf.

[70] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S. and Gill, J., 2011. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American Journal of Transplantation*, 11(10), pp.2093-2109.

[71] Durand, C.M., Zhang, W., Brown, D.M., Yu, S., Desai, N., Redd, A.D., Bagnasco, S.M., Naqvi, F.F., Seaman, S., Doby, B.L. and Ostrander, D., 2021. A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action. *American Journal of Transplantation*, 21(5), pp.1754-1764.

graft survival, rejections, HIV breakthrough or severe adverse events.[72] A recent "observational study of kidney transplantation in persons with HIV, transplantation from donors with HIV appeared to be noninferior to that from donors without HIV."[73] Another study finds that kidney transplantation yields survival benefits for people living with HIV with end-stage renal disease (ESRD) compared to dialysis.[74] Another study documents some of the history of organ transplantation and HIV, including to identify successful partial liver transplants from donors with HIV outside of the United States.[75] These studies contribute to our conclusion that the potential benefits of the final rule experienced by transplant recipients will be substantial.

2. Impacts of Kidney Transplants on Mortality

To estimate the average change in life expectancy for kidney transplant recipients, we adopt estimates from a study that found, "Overall, the projected years of life remaining were 10 for patients who remained on the waiting list and 20 for those who received a transplant."[76]

We model this impact as an incremental increase in 1 statistical life year per transplant recipient for each of 10 years, beginning 10 years in the future. We convert this impact into the present value of the change in life expectancy using the following formula:

$$\sum_{t=m}^{n-1} r^t = \frac{r^m - r^n}{1 - r}$$

Adopting parameters m = 10, n = 20, and r = 1/(1+2%), this expression evaluates to 7.5 life years, which we adopt as the present value of the average increase in life expectancy per kidney transplant recipient.

This measure of life expectancy gain might be underestimated or overestimated for several reasons. All else equal, it may be underestimated since the finding predates increases in long-term patient survival rates and reductions in death and graft loss after kidney transplantation observed in more recent cohorts of transplant recipients.[77] However, we note that in the decade prior to the COVID-19 pandemic, "[a]djusted all-cause mortality among prevalent patients with ESRD decreased by 12.7%, from 147.2 to 128.5 per 1000 person-years, from 2011 to 2019,"

[72] Durand, C.M., Florman, S., Motter, J.D., Brown, D., Ostrander, D., Yu, S., Liang, T., Werbel, W.A., Cameron, A., Ottmann, S. and Hamilton, J.P., 2022. HOPE in action: a prospective multicenter pilot study of liver transplantation from donors with HIV to recipients with HIV. *American Journal of Transplantation*, 22(3), pp.853-864.

[73] Durand, C.M., Massie, A., Florman, S., Liang, T., Rana, M.M., Friedman-Moraco, R., Gilbert, A., Stock, P., Mehta, S.A., Mehta, S. and Stosor, V., 2024. Safety of Kidney Transplantation from Donors with HIV. *New England Journal of Medicine*, 391(15), pp.1390-1401.

[74] Locke, J.E., Gustafson, S., Mehta, S., Reed, R.D., Shelton, B., MacLennan, P.A., Durand, C., Snyder, J., Salkowski, N., Massie, A. and Sawinski, D., 2017. "Survival benefit of kidney transplantation in HIV-infected patients." *Annals of Surgery*, 265(3), pp.604-608.

[75] Botha, J., Fabian, J., Etheredge, H., Conradie, F. and Tiemessen, C.T., 2019. HIV and solid organ transplantation: where are we now. *Current HIV/AIDS Reports*, 16, pp.404-413.

[76] Wolfe, R.A., Ashby, V.B., Milford, E.L., Ojo, A.O., Ettenger, R.E., Agodoa, L.Y., Held, P.J. and Port, F.K., 1999. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. *New England Journal of Medicine*, 341(23), pp.1725-1730. Quoted from page 1728.

[77] Hariharan, S., Israni, A.K. and Danovitch, G., 2021. Long-term survival after kidney transplantation. *New England Journal of Medicine*, 385(8), pp.729-743.

with decreases in mortality rates observed for patients receiving dialysis as well as for kidney transplant recipients.[78] Thus, since our measure of life expectancy gain is based on differences in life expectancy between kidney dialysis patients and kidney transplant recipients, the potential direction of bias is unclear. As an additional consideration, the average life expectancy gain might be different for the populations receiving organs because of the final rule, which may differ in various ways from the general population; however, long-term outcomes for transplant recipients, including patient survival and graft survival, are comparable regardless of HIV status.[79]

3. Impacts of Liver Transplants on Mortality

We also estimate the average change in life expectancy for liver transplant recipients. One complicating factor is that survival outcomes for liver transplant recipients depend heavily on the severity of the condition of the transplant candidate. OPTN has adopted a model for end-stage liver disease to assign priority to most liver transplant candidates based on their medical urgency:

> "When being listed for a liver transplant, candidates receive a model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score, which is calculated using a combination of the candidate's clinical lab values. These scores are designed to reflect the probability of death on the waitlist within a 90-day period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned status 1A or 1B."[80]

To give a sense of the variability, one study estimated survival outcomes for patients remaining on the waitlist by MELD score. At 3 months, survival rates were "91% for a MELD score of 20, 58% for 29, 52% for 30, and 10% for 39."[81] Another study found that patients with a MELD score of 40 "have a 3-month survival probability of almost 0% without [liver transplantation]."[82] We note, however, that both studies applied scores that predate a July 13, 2023 update[83] to the data used in the MELD calculation formula.

To quantify the change in life expectancy for liver transplant recipients attributable to the final rule, we adopt estimates from a study that estimated survival benefits of liver transplants that

---

[78] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. October 31, 2023. United States Renal Data System 2023 Annual Data Report. End Stage Renal Disease, Chapter 6. https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/6-mortality.

[79] Zarinsefat, A., Gulati, A., Shui, A., Braun, H., Rogers, R., Hirose, R., Ascher, N. and Stock, P., 2022. Long-term outcomes following kidney and liver transplant in recipients with HIV. *JAMA Surgery*, 157(3), pp.240-247.

[80] Organ Procurement and Transplantation Network. June 27, 2022. "Notice of OPTN Policy and Guidance Changes, Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B." https://optn.transplant.hrsa.gov/media/3idbp5vq/policy-guid-change_impr-liv-alloc-meld-peld-sta-1a-sta-1b_liv.pdf.

[81] VanDerwerken, D.N., Wood, N.L., Segev, D.L. and Gentry, S.E., 2021. The precise relationship between model for end-stage liver disease and survival without a liver transplant. *Hepatology*, 74(2), pp.950-960.

[82] Vernadakis, S., Paul, A., Gercken, G. and Sotiropoulos, G., 2014. Liver Transplantation for MELD-Score 40 Patients: Preliminary Results and Single Center Experience.: Abstract# B1097. *Transplantation*, 98, p.729.

[83] Organ Procurement and Transplantation Network. "MELD Calculator." https://optn.transplant.hrsa.gov/data/allocation-calculators/meld-calculator/.

vary by MELD score.[84] For patients with a MELD of 31-34, the study estimated a gain of 6.9 life years, and for patients with a MELD of 34-40, a gain of 7.2 life years. We adopt the unweighted average across these patient groups of 7.05 life years as an undiscounted change in life expectancy for liver transplant recipients. To account for timing, we assume that these individuals would have a remaining life expectancy of 0.25 years without liver transplantation. We follow the same process to account for timing as with kidney transplants, but adopt parameters m = 0.25, n = 7.30, and r = 1/(1+2%). This expression evaluates to 6.6 life years, which we adopt as the present value of the average increase in life expectancy per liver transplant recipient.

4. Impacts of Transplants on Morbidity

We anticipate that the final rule will also result in improvements in the health-related quality of life for individuals receiving kidney[85] and liver[86] transplants. For impacts associated with kidney transplantation, we identify one study that summarizes estimates of the health-related quality-of-life reported by both kidney transplant recipients and dialysis patients. This meta-analysis finds that kidney transplant recipients experience a mean utility score that is 0.11 higher than dialysis patients.[87] We adopt this score as our primary estimate of the improvement in quality of life experienced by kidney transplant recipients. When modeling this parameter, we adopt a normal distribution with mean 0.11 and standard deviation 0.02, matching the coefficient estimate and standard error reported in the study. Over ten years, corresponding to the time period prior to the impacts on mortality, this difference sums to 1.1 undiscounted quality-adjusted life years (QALYs) as our primary estimate.[88] Accounting for timing by applying a constant 2% discount rate, this is a present value of a 0.99 QALY gain on average per kidney transplant. We are not aware of a comparable estimate that would readily enable quantification of the improvements in the health-related quality of life for individuals receiving liver transplants in the context of the final rule.

5. Valuing Mortality and Morbidity Risk Reductions

The HHS *Guidelines for Regulatory Impact Analysis*[89] discuss an approach to valuing mortality risk reductions based on estimates of individual willingness to pay, commonly referred to as the

[84] Luo, X., Leanza, J., Massie, A.B., Garonzik-Wang, J.M., Haugen, C.E., Gentry, S.E., Ottmann, S.E. and Segev, D.L., 2018. MELD as a metric for survival benefit of liver transplantation. *American Journal of Transplantation*, 18(5), pp.1231-1237.
[85] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S. and Gill, J., 2011. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American Journal of Transplantation*, 11(10), pp.2093-2109.
[86] Girgenti, R., Tropea, A., Buttafarro, M.A., Ragusa, R. and Ammirata, M., 2020. Quality of life in liver transplant recipients: a retrospective study. *International Journal of Environmental Research and Public Health*, 17(11), p.3809.
[87] Wyld, M., Morton, R.L., Hayen, A., Howard, K. and Webster, A.C., 2012. "A systematic review and meta-analysis of utility-based quality of life in chronic kidney disease treatments." PLoS Med. 2012;9(9):e1001307.
[88] Quality-adjusted life years (QALYs) are a nonmonetary measure that integrates the duration and severity of illness. QALYs are derived by multiplying the amount of time an individual spends in a health state by a measure of the health-related quality of life associated with that state.
[89] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. "Guidelines for Regulatory Impact Analysis." https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.

value per statistical life (VSL). HHS's VSL estimates are based on a criteria-driven literature review that identifies values that are suitable for use in its regulatory impact analyses.[90] The *Guidelines* and an appendix published subsequently[91] provide background information on the VSL estimates, including technical guidance on applying the estimates and the process for updating these values. For mortality risk changes occurring in 2024, HHS adopts $6.1 million, $13.1 million, and $19.9 million for the low, central, and high estimates of VSL, respectively. The HHS *Guidelines* also outline HHS's approach to estimating the Value per Statistical Life Year (VSLY), which is used in analyses that monetize changes to life expectancy measured in years. This approach is designed to be consistent with the VSL estimates, life expectancy data, and the approach to discounting used in regulatory analysis. HHS computes VSLY by dividing VSL by an estimate of discounted future life years. Specifically, we calculate the expected present value of remaining life years for an individual 40 years of age, consistent with the average age reported in the literature review of VSL studies, accounting for age-specific survival probabilities. For the most recent life expectancy data,[92] an individual 40 years of age has a remaining life expectancy of 38.8 years. When applying a constant 2% discount rate, the present value is 26.5 years. For impacts occurring in 2024 that will result in changes to life expectancy, we adopt $231,000, $495,000, and $754,000 for the low, central, and high estimates of Value per Statistical Life Year (VSLY), respectively.

The HHS *Guidelines* discuss several approaches to valuing morbidity risk reductions, including one approach that monetizes benefits that are quantified using QALYs by multiplying by an estimate of the value per QALY (VQALY).[93] HHS computes VQALY similar to VSLY, except this metric incorporates measurements of age-varying, but otherwise population-average, health-related quality-of-life scores.[94] Based on these scores and the data and other assumptions used to compute remaining life expectancy, we calculate that an individual 40 years of age has a present value of 22.2 remaining QALYs. For morbidity risk changes or other health-related quality-of-life changes occurring in 2024, we adopt $276,000, $591,000, and $899,000 for the low, central, and high estimates of VQALY, respectively.

HHS's estimates of VSL, VSLY, and VQALY increase over time in real terms, consistent with a long-term annual growth rate for real earnings of 1.0%[95] and an assumption that the VSL income

---

[90] Robinson, L.A. and Hammitt, J.K., 2016. "Valuing reductions in fatal illness risks: Implications of recent research." *Health Economics*, 25(8), pp. 1039-1052.

[91] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2021. "Appendix D: Updating Value per Statistical Life (VSL) Estimates for Inflation and Changes in Real Income." https://aspe.hhs.gov/reports/updating-vsl-estimates.

[92] Centers for Disease Control and Prevention. November 7, 2023. "United States Life Tables, 2021." Table 1. Life table for the total population: United States, 2021. https://www.cdc.gov/nchs/data/nvsr/nvsr72/nvsr72-12.pdf.

[93] Consistent with current guidance to Federal agencies on the development of regulatory analysis, QALYs are "used only in the portion of the analysis that focuses on non-fatal injury or illness." See U.S. Office of Management and Budget. 2023. Circular A-4, "Regulatory Analysis." https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf. Page 49, footnote 90.

[94] Hamner, J., W.F. Lawrence, J.P. Anderson, R.M. Kaplan, and D.G. Fryback. 2006. "Report of Nationally Representative Values for the Noninstitutionalized US Adult Population for 7 Health-Related Quality-of-Life Scores." *Medical Decision Making* 26(4), pp. 391-400.

[95] Congressional Budget Office. June 2023. "The 2023 Long-Term Budget Outlook." Table C-1. Average Annual Values for Additional Economic Variables That Underlie CBO's Extended Baseline Projections: Growth of Real Earnings per Worker, Overall, 2023-2053. https://www.cbo.gov/publication/59014.

elasticity is 1.0. Unrounded estimates of HHS's standard values used in this analysis are available online.[96]

For kidney transplants occurring in 2024, we adopt a value of mortality risk reductions per transplant of $3.7 million, equal to the 7.5 statistical life years calculated above times the central estimate of VSLY of $495,000; we also adopt a value of morbidity risk reductions per transplant of $584,000, equal to the 0.99 QALYs calculated above times the central estimate of VQALY of $591,000. Combined, the total value of risk reductions is about $4.3 million per kidney transplant. For liver transplants occurring in 2024, we adopt a value per transplant of about $3.2 million, equal to the 6.6 statistical life years calculated above times the same VSLY. Table 4, below, reports primary estimates of the annual impacts on kidney transplants, and associated health benefits, and Table 5 reports comparable estimates for livers.

6. Time Savings from Fewer Kidney Dialysis Treatments

We also identify benefits from time savings associated with fewer kidney dialysis treatments. To quantify these impacts, we adopt an assumption that dialysis "[t]reatments usually last about four hours and are done three times per week."[97] We also assume that dialysis patients spend, on average, an additional half hour for a round-trip traveling to each treatment.[98] Over the course of a year, this is about 704.4 hours per year for each patient on dialysis.[99] Over ten years, this is about 7,044 hours, or about 6,327 hours in present value terms using a 2% discount rate. This approach might underestimate the total time associated with kidney dialysis treatments, as it does not account for additional time spent by caregivers, including the time traveling with dialysis patients to treatments.

To estimate the time-saving benefits of the final rule, we monetize the opportunity cost of the time that would have been spent on dialysis. We apply an estimate of an hourly value of time of $19.24,[100] following HHS's default approach to monetizing changes in time use for unpaid activities.[101] This default estimate might underestimate the benefits experienced by individuals,

---

[96] Kearsley, A. "HHS Standard Values for Regulatory Analysis, 2024." Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. January 2024. https://aspe.hhs.gov/reports/standard-ria-values.

[97] National Kidney Foundation. January 2, 2023. "Dialysis." https://www.kidney.org/atoz/content/dialysisinfo.

[98] Travel time to dialysis appointments likely varies significantly by patient. In a study measuring distance traveled for dialysis treatment, patients living in counties with 3 or more dialysis facilities traveled an average of 5.5 miles, measured as "the distance between patients' home addresses and the dialysis facility at the time they initiated treatment," while individuals living in counties with 0 dialysis facilities traveled 25.2 miles; 1 facility, 12.1 miles; and 2 facilities, 8.6 miles. Velázquez, A. F., Thorsness, R., Trivedi, A. N., & Nguyen, K. H., 2022. "County-Level Dialysis Facility Supply and Distance Traveled to Facilities among Incident Kidney Failure Patients." Kidney360, 3(8), pp.1367–1373. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9416828/.

[99] (4 hours per session + 0.5 hours per round trip) * (3 sessions per week) * (365.25 days per year) / (7 days per week) ≈ 704 hours per year.

[100] Kearsley, A. "HHS Standard Values for Regulatory Analysis, 2024." Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. January 2024. https://aspe.hhs.gov/reports/standard-ria-values.

[101] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices." https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.

since it does not account for the discomfort some individuals experience during treatment;[102] however, some of this averted discomfort may be accounted elsewhere in this analysis as improvements in the health-related quality of life for individuals receiving kidney transplants. Applying this estimate of the hourly value of time with the present value estimate of the time spent on kidney dialysis visits, we calculate $121,740 in time-saving benefits per individual.[103] Table 4, below, reports primary estimates of the time-saving benefits associated with kidney transplants.

7. Discussion of Benefits

Table 4 reports our primary estimates of the benefits from kidney transplants attributable to the final rule and Table 5 reports our primary estimates from liver transplants. We identify several additional sources of benefits not otherwise captured in these monetized benefits. First, we anticipate some quality-of-life improvements for liver transplant recipients; however, we did not identify an estimate that would readily enable quantification of these improvements, such as the estimated average utility score improvement used to quantify the health-related quality-of-life for kidney transplant recipients. Second, we anticipate additional time savings associated with reductions in time spent by caregivers. Third, for a small share of kidney dialysis patients that receive hemodialysis at home,[104] we might anticipate additional benefits associated with reductions in patient-borne utility costs.[105]

[102] National Kidney Foundation. August 12, 2024. "Dialysis: Filtering Myths from Facts." https://www.kidney.org/news-stories/dialysis-filtering-myths-facts.

[103] As noted, this analysis does not explicitly account for changes in time use by caregivers, and we monetize the change in time use by applying a value of time that does not account for potentially relevant factors such as discomfort during kidney dialysis. As a sensitivity analysis, we considered accounting for these and other factors by multiplying the default value of time by 2. This would increase the time-saving benefit per individual to about $243,000. Doubling the time-saving benefits would increase the present value and annualized total benefits from kidney transplants reported in Table 4 by about 3%.

[104] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. 2023. "United States Renal Data System 2023 Annual Data Report." Figure 1.6 Prevalent ESRD by modality, 2000-2020. https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities.

[105] Nickel, M., Rideout, W., Shah, N., Reintjes, F., Chen, J.Z., Burrell, R. and Pauly, R.P., 2017. Estimating patient-borne water and electricity costs in home hemodialysis: a simulation. *Canadian Medical Association Open Access Journal*, 5(1), pp.E61-E65. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378499/.

Table 4. Benefits Associated with Kidney Transplants ($ millions)

Year	Impact on Transplants	Health Benefit per Transplant	Time-Saving Benefit per Transplant	Health Benefits	Time-Saving Benefits	Total Benefits
2025	0	$4.3	$0.1	$0	$0	$0
2026	26	$4.4	$0.1	$116	$3	$119
2027	53	$4.4	$0.1	$234	$6	$240
2028	79	$4.5	$0.1	$354	$10	$363
2029	97	$4.5	$0.1	$437	$12	$449
2030	104	$4.6	$0.1	$473	$13	$486
2031	105	$4.6	$0.1	$486	$13	$499
2032	105	$4.7	$0.1	$491	$13	$504
2033	105	$4.7	$0.1	$496	$13	$509
2034	105	$4.8	$0.1	$501	$13	$514
Present Value (2%)	683			$3,142	$83	$3,226
Annualized (2%)	76			$350	$9	$359

Note: Health benefits include reductions in mortality and morbidity risks.

Table 5. Benefits Associated with Liver Transplants ($ millions)

Year	Impact on Transplants	Health Benefit per Transplant	Health Benefits
2025	0	$3.3	$0
2026	25	$3.3	$84
2027	50	$3.4	$169
2028	75	$3.4	$256
2029	92	$3.4	$316
2030	99	$3.5	$343
2031	100	$3.5	$352
2032	100	$3.5	$356
2033	100	$3.6	$359
2034	100	$3.6	$363
Present Value (2%)	651		$2,275
Annualized (2%)	72		$253

Note: Health benefits are mortality risk reductions.

F. Costs and Cost Savings of the Final Rule

This section describes our approach to quantifying and monetizing costs and transfers associated with transplantation. For liver transplants, we adopt estimates of the medical expenditures associated with transplantation as the cost per transplant, and for kidney transplants, we identify a primary estimate of the net cost per transplant based on a study that also identifies partially offsetting reductions in medical expenditures related to kidney dialysis. We then incorporate

estimates of the annual real growth rate for these cost estimates to account for observed increases over time in the inflation-adjusted costs associated with transplantation. We report the 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.

1. Medical Expenditures Associated with Transplantation

We considered several sources of per-transplant cost estimates. One study reports average billed charges associated with transplantation, including procurement, hospital transplant admission, medical costs during a period prior to and after hospital transplant admission, and the costs of immunosuppressants and other prescription drugs. This study reports the total billed charges of $520,962 per kidney and $1,034,153 per liver.[106] One advantage of these estimates for our purposes is that they cover the pre-, intra-, and post-transplant costs on all organs using a consistent cost-estimating methodology. Unfortunately, accurate medical cost estimates are not publicly available from health insurance firms, since the network discounts received by private firms are generally treated as trade secrets, and Medicare's payments are typically not based directly on costs (with some exceptions). Hence, Milliman uses "charges" for its estimates. As with likely excess of charges over costs, there is a netting off of non-transplantation costs—that is, costs associated with organ failure that are not affected by transplantation itself. In a prior analysis of final rulemaking related to organ procurement, HHS assumed that these divergences between costs and charges largely cancel each other out, with the net effect that anticipated first-year costs are about 20 percent less than charge estimates.[107] That analysis also identified ongoing annual costs associated with immunosuppressant drugs not included in the charge estimates, accounting for these costs for the next 4 years. For this analysis, we adopt a similar framework, but instead assume that the present value of the incremental expenditures on immunosuppressant drugs matches the difference between actual first-year costs and the charge estimates. Thus, we adopt the $1,034,153 per liver transplant estimates as approximating the present value of the costs per liver transplant.

For kidneys, we adopt estimates from a study that compared costs associated with kidney transplantations to dialysis, using Medicare claims data with Medicare as the primary payer linked to national registry and hospital cost-accounting data. This study found that patients on dialysis incur medical expenses of $370,858 over 10 years, while patients receiving increased-risk donor organs incur expenses of $389,819 over 10 years.[108] From these estimates, we derive a $18,961 net increase in medical expenditures, which we adopt as our primary estimate of the cost per kidney transplant. In a sensitivity analysis reported in Section II.H, we consider two alternative estimates of the cost per kidney transplant: one corresponding to a simulation that

[106] Bentley, T.S. and Ortner, N.J., 2020. 2020 US organ and tissue transplants: Cost estimates, discussion, and emerging issues. Milliman Research Report. https://member.aanlcp.org/wp-content/uploads/2021/03/2020-US-organ-tissue-transplants.pdf. Cost estimates, originally reported in 2020 dollars inflated to 2023 constant dollars.
[107] Centers for Medicare & Medicaid Spending. December 2, 2020. "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" final rule. https://www.federalregister.gov/d/2020-26329/p-483.
[108] Axelrod D.A., Schnitzler M.A., Xiao H., et al. 2018. "An Economic Assessment of Contemporary Kidney Transplant Practice." *American Journal of Transplantation*, 18: 1168-1176. Cost estimates are present values using an annual discount rate of 3%, originally reported in 2016 dollars inflated to 2023 constant dollars.

adopts similar assumptions as our primary estimate over a longer time horizon, and a second based on alternative estimates from a different study.

We report the net impact on medical expenditures as the costs of the final rule, and separately report the partially offsetting cost-saving impacts as distributional impacts, which represent a net transfer in monetary payments that will go to entities providing medical care associated with kidney dialysis to entities providing medical care associated with kidney transplantation.

2. Growth in Medical Expenditures

Our base estimate of the cost per liver transplant of $1,034,153 is reported in constant 2023 dollars and corresponds to transplants occurring in 2020. For transplants occurring in 2017, the inflation-adjusted cost per liver transplant was $1,009,997,[109] indicating that the average cost per liver transplant increased in real terms over this three-year period by about 2.4%, or about 0.8% annually. Similarly, the cost per kidney transplant has increased over this three-year period by about 1.0%, or about 0.3% annually. When considering the annual costs and transfers associated with transplants under the final rule, we incorporate a 0.8% real growth rate for impacts associated with liver transplants and a 0.3% growth rate for impacts associated with kidney transplants. From a base year of 2020, this adjustment increases our estimate of the cost per liver transplant to $1,075,705 in 2025; and from a base year of 2016, our estimate of the cost per kidney transplant to $19,555. Table 6 reports primary estimates of the impacts on kidney transplants and the costs and transfers associated with those transplants for each year of the analysis. Table 7 reports primary estimates of the impacts on liver transplants and the costs associated with those transplants.

[109] Bentley, T.S. and Phillips, S.J., 2017. 2017 U.S. organ and tissue transplant cost estimates and discussion. Milliman Research Report. https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2017/2017-transplant-report.ashx. Cost estimates, originally reported in 2017 dollars inflated to 2023 constant dollars.

Table 6. Costs and Transfers Associated with Kidney Transplants ($ millions)

Year	Impact on Transplants	Costs per Transplant	Transfers per Transplant	Costs	Transfers
2025	0	$0.02	$0.38	$0.0	$0.0
2026	26	$0.02	$0.38	$0.5	$10.1
2027	53	$0.02	$0.39	$1.0	$20.3
2028	79	$0.02	$0.39	$1.6	$30.5
2029	97	$0.02	$0.39	$1.9	$37.4
2030	104	$0.02	$0.39	$2.1	$40.3
2031	105	$0.02	$0.39	$2.1	$41.1
2032	105	$0.02	$0.39	$2.1	$41.3
2033	105	$0.02	$0.39	$2.1	$41.4
2034	105	$0.02	$0.39	$2.1	$41.5
Present Value (2%)	683			$13.6	$266.5
Annualized (2%)	76			$1.5	$29.7

Notes: costs are measured as the net impact on medical expenditures; transfers are the shifts in expenditures associated with kidney dialysis to expenditures associated with kidney transplantation.

Table 7. Costs Associated with Liver Transplants ($ millions)

Year	Impact on Transplants	Costs per Transplant	Costs
2025	0	$1.08	$0.0
2026	25	$1.08	$27.2
2027	50	$1.09	$54.8
2028	75	$1.10	$82.8
2029	92	$1.11	$102.0
2030	99	$1.12	$110.3
2031	100	$1.13	$113.1
2032	100	$1.14	$114.0
2033	100	$1.15	$114.9
2034	100	$1.15	$115.8
Present Value (2%)	651		$731.5
Annualized (2%)	72		$81.4

3. Time Reading and Understanding the Final Rule

We anticipate that most transplant centers with at least one active transplant program will incur costs associated with becoming familiar with the final rule. To quantify this impact, we estimate the time spent to read and understand the final rule. We estimate that it will take an individual

about 45 minutes to read the final rule.[110] We assume that, on average, one individual at each transplant center will read the final rule. Thus, across 248 transplant centers, this will amount to about 186 hours.[111]

To monetize the change in time use associated with these activities, we adopt an hourly value of time based on the cost of labor, including wages and benefits, and also indirect costs, which "reflect resources necessary for the administrative oversight of employees and generally include time spent on administrative personnel issues (e.g., human resources activities such as hiring, performance reviews, personnel transfers, affirmative action programs), writing administrative guidance documents, office expenses (e.g., space rental, utilities, equipment costs), and outreach and general training (e.g., employee development)."[112]

For this impact, we identify a pre-tax hourly wage for medical and health services managers. According to the U.S. Bureau of Labor Statistics, the median hourly wage for these individuals is $53.21 per hour.[113] We assume that benefits plus indirect costs equal approximately 100 percent of pre-tax wages, and adjust this hourly rate by multiplying by two, for a fully loaded hourly wage rate of $106.42. We multiply this fully loaded hourly wage rate by the 185 total hours across all transplant centers and estimate a one-time cost of $19,794.

4. Time Reviewing Policies and Procedures, and Training Staff

The final rule will likely result in some additional transplant centers choosing to transplant kidneys and livers from donors with HIV. To produce an upper-bound estimate, we begin with 248 total transplant centers with active programs, subtract 14 centers that do not have a kidney or liver program, and further subtract 28 centers that have HOPE Act IRB approval under the baseline scenario. This leaves 206 transplant centers as our upper-bound estimate. For the purposes of this analysis, we adopt a primary estimate of 103 transplant centers by assuming that half will choose to transplant kidneys and livers from donors with HIV.

We anticipate that each of these transplant centers will incur costs associated with reviewing their policies and procedures and training staff prior to transplanting kidneys and livers from donors with HIV. To quantify these impacts, we assume that an individual at each transplant center will spend about 16 hours on average to review and, if necessary, update their policies, procedures, and training materials. Across 103 transplant centers, this is 1,648 total hours. To monetize this impact, we adopt the fully loaded wage rate of $106.42 for medical and health services manager described above. We multiply this fully loaded wage rate by the 1,648 total hours across all transplant centers and estimate a one-time cost of $175,380. We further assume that staff at each center will spend an average of 40 hours on training, inclusive of total time spent by staff delivering and receiving training. Across 103 transplant centers, this is 4,120 total

[110] This estimate is consistent with an individual reading the final rule, which contains about 10,000 words, at approximately 200 to 250 words per minute.
[111] 248 * 45 minutes = 11,160 minutes = 186 hours.
[112] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices." https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework. Page 13.
[113] U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2023. 11-9111 Medical and Health Services Managers. Median hourly wage. https://www.bls.gov/oes/current/oes119111.htm.

hours. For this impact, we identify a pre-tax hourly wage for health practitioners and technical occupations of $38.86 per hour,[114] and compute a fully loaded hourly wage rate of $77.72. We multiply this fully loaded wage rate by 4,120 total hours across all transplant centers and estimate a one-time cost of $320,206.

5. Discussion of Costs and Cost Savings

Table 8 summarizes our primary estimates of the costs associated with the final rule. We model the one-time costs associated with reading and understanding the final rule, reviewing policies and procedures, and training staff as occurring in 2025, the first year of the time horizon of our analysis. We identify several potential sources of costs not otherwise captured in these monetized impacts. First, the incremental costs associated with organ transplants from donors with HIV might be higher than estimates covering a broader population. Second, by lifting the research requirement, the final rule potentially forgoes some information and data that would be gathered from research and trials occurring under the baseline scenario; however, we also anticipate corresponding cost savings associated with less time spent related to IRB requirements, data collection, and analysis of clinical trial data. These cost savings will likely accrue to the 28 centers with HOPE Act IRB approval.

We also weighed the possibility of costs associated with adverse impacts, such as accidental or inadvertent transmission of HIV in the performance of HOPE Act transplants; however, as noted in public comments by OPTN,[115] "the OPTN reviewed data safety monitoring board (DSMB) data reports from five years covering more than 300 HOPE Act transplants, and no DSMB identified any patient safety concerns. In addition, as noted in the proposed rule, no reports have been made to the OPTN of safety issues regarding HOPE Act transplants among organ procurement organization (OPO), hospital, or transplant program personnel or in patients, in donor hospitals, or in transplant hospitals." Thus, we do not anticipate any increases in risks of this nature under the final rule.

[114] U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2023. 29-0000 Healthcare Practitioners and Technical Occupations (Major Group). https://www.bls.gov/oes/current/oes290000.htm.
[115] Regulations.gov Docket (HRSA-2024-0001). Comment ID HRSA-2024-0001-0016.

Table 8. Costs of the Final Rule ($ millions)

Year	Kidney Transplants	Liver Transplants	Reading and Understanding	Policies and Procedures	Training	Total
2025	$0.00	$0.00	$0.02	$0.18	$0.32	$0.52
2026	$0.52	$27.18	$0.00	$0.00	$0.00	$27.70
2027	$1.04	$54.79	$0.00	$0.00	$0.00	$55.83
2028	$1.56	$82.84	$0.00	$0.00	$0.00	$84.40
2029	$1.91	$102.05	$0.00	$0.00	$0.00	$103.96
2030	$2.06	$110.33	$0.00	$0.00	$0.00	$112.39
2031	$2.10	$113.09	$0.00	$0.00	$0.00	$115.19
2032	$2.11	$113.98	$0.00	$0.00	$0.00	$116.09
2033	$2.12	$114.89	$0.00	$0.00	$0.00	$117.00
2034	$2.12	$115.79	$0.00	$0.00	$0.00	$117.92
Present Value (2%)	$13.62	$731.54	$0.02	$0.17	$0.31	$745.67
Annualized (2%)	$1.52	$81.44	$0.00	$0.02	$0.03	$83.01

G. Analysis of Regulatory Alternatives to the Final Rule

We consider and assess three regulatory alternatives to the final rule. This section describes the general policy approach and the benefits, costs, transfers, and net benefits for each of these alternatives, measured against a common baseline scenario. This analysis is limited to an assessment of economic efficiency and distributional consequences of the regulatory alternatives, and does not speak to the legal viability of any alternative.[116] Further, although we quantify and monetize some of the economic impacts of the alternatives by combining data with analytic assumptions, we also note and consider differences in the likely effects across the alternatives that we are not able to quantify.

To simplify the narrative, we have assigned each regulatory alternative a name that relates to the types of organs from donors with HIV that would be available for transplantation without the research and IRB requirements under the alternatives. Table 9 reports our estimates of the number of organ transplants occurring under our baseline scenario, the final rule, the "kidneys only" alternative, the "livers only" alternative, and the "all organs" alternative. Table 10 reports our estimates of the incremental impacts of the final rule and regulatory alternatives on transplants when the effects fully materialize. Table 11, Table 12, and Table 13 report the annual economic impacts associated with additional transplants occurring under the "all organs"

[116] "If legal or other constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Orders 12866, you may consider identifying these constraints and estimating their opportunity cost (and effects more generally). Such information may, for example, be useful to Congress under the Regulatory Right-to-Know Act or in considering statutory reforms." U.S. Office of Management and Budget. November 9, 2023. "Circular No. A-4: Regulatory Analysis." https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf. Pages 22-23.

alternative for hearts, lungs, and pancreases. Table 14 summarizes the economic impacts associated with the final rule and three regulatory alternatives.

1. "Kidneys Only" Alternative

We assess the regulatory alternative of lifting the research and IRB requirements for only kidneys, leaving the requirements in place for livers and other organs. Under this alternative, we would anticipate the same benefits from kidney transplants reported in Table 4, and the same costs and transfers reported in Table 6.

2. "Livers Only" Alternative

We assess the regulatory alternative of lifting the research and IRB requirements for only livers, leaving the requirements in place for kidneys and other organs. Under this alternative, we would anticipate the same benefits from liver transplants reported in Table 5, and the same costs reported in Table 7.

3. "All Organs" Alternative

We assess the regulatory alternative of lifting the research and IRB requirements for all organs. Under this alternative, we would anticipate similar benefits, costs, and transfers under the final rule, plus additional impacts associated with any incremental changes in transplants other than kidneys and livers. For this analysis, we follow a similar analytic approach as our assessment of the final rule while also noting several data limitations beyond those encountered and addressed in that analysis. We focus this analysis on hearts, lungs, and pancreases, for which we have some limited data, while this alternative would also remove the research and IRB requirements for other organs.

a. Baseline Conditions

We extend the baseline scenario described in our analysis of the final rule to adopt projections of about 0.5 heart transplants, 0 lung transplants, and 0 pancreas transplants per year, absent any additional regulatory action. These estimates correspond to the average yearly transplants occurring under the HOPE Act between January 1, 2016 and October 4, 2024.

b. Impacts on Transplants

Our analysis of the final rule identifies three studies that project the number of kidneys and livers potentially available for transplant. These studies do not contain projections for hearts, lungs, pancreases, or other organs. We are not aware of and did not receive public comments identifying other studies containing comparable projections for other organs. Strictly for the purposes of this analysis, we adopt additional assumptions that enable us to extrapolate our estimates of the impacts on kidney and liver transplants under the final rule to estimate the impacts on heart, lung, and pancreas transplants under this alternative.

In 2023, kidney and liver transplant recipients combined make up about 83.5% of total transplant recipients, with 9.8% receiving a heart transplant, 6.5% receiving a lung transplant, and 0.2%

receiving a pancreas transplant.[117] Under this alternative, if the incremental impacts on heart, lung, and pancreas transplants were proportional to our estimates of the incremental impacts on kidney and liver transplants, we would anticipate 32 additional heart, 22 lung, and fewer than 1 pancreas transplants per year.[118] We interpret these to be upper-bound estimates, and adopt primary estimates that are 50% lower. Since our extrapolations are based on estimates of the impact on kidneys and livers that already account for other factors such as consent for organ donation and transplants from living donors, we do not make any additional adjustments for these factors. To account for timing of the impacts on transplants, we adopt an implementation timeline that matches our analysis of the final rule when reporting the economic impacts associated with heart, lung, and pancreas transplants in subsequent sections of this analysis.

Table 9. Annual Transplants: Baseline, Final Rule, and Regulatory Alternative Scenarios

Organ	Baseline	Final Rule	Kidneys Only	Livers Only	All Organs
Heart	0.5	0.5	0.5	0.5	16.5
Kidney	60.4	165.7	165.7	60.4	165.7
Liver	11.5	111.7	11.5	111.7	111.7
Lung	0.0	0.0	0.0	0.0	10.8
Pancreas	0.0	0.0	0.0	0.0	0.4

Table 10. Annual Impacts on Transplants: Final Rule, and Regulatory Alternatives

Organ	Final Rule	Kidneys Only	Livers Only	All Organs
Heart	0.0	0.0	0.0	16.0
Kidney	105.3	105.3	0.0	105.3
Liver	100.3	0.0	100.3	100.3
Lung	0.0	0.0	0.0	10.8
Pancreas	0.0	0.0	0.0	0.4

c. Benefits

Our analysis of the final rule quantifies the life expectancy gains for both kidney and liver transplant recipients, and additional sources of benefits for kidney transplant recipients. We discuss several sources of uncertainty that might cause those benefits to be underestimated or overestimated. We also summarize the findings from research confirming the significant benefits of kidney and liver transplantation for transplant recipients with HIV receiving organs from donors with HIV. At the time of drafting this final RIA, less research is available for heart, lung, and pancreas transplant recipients with HIV or for transplants under the HOPE Act; however, some evidence is available, such as a study that identifies comparable survival rates for heart and

[117] Health Resources and Services Administration. Organ Donation and Transplantation. Analysis of data from 2023. https://data.hrsa.gov/topics/health-systems/organ-donation. For these summary statistics, which are used later for extrapolation, we classify "kidney-pancreas" organ transplant recipients as kidney transplant recipients.
[118] The impacts on transplants are rounded to the nearest whole number, but calculated using unrounded estimates.

lung transplant recipients regardless of HIV status.[119] For the purposes of quantifying the approximate magnitude of the health benefits under this alternative, we continue with the analysis, but return to this issue when summarizing and comparing the economic impacts of the alternatives. Our analysis focuses on mortality risk reductions, and we quantify impacts associated with heart, lung, and pancreas transplants, for which we have more data. This regulatory alternative would also potentially result in small impacts for other organs that we do not quantify in this analysis. For example, among single-organ transplants performed in the U.S., about 0.1% are intestine transplants.[120]

d. Impacts of Heart Transplants on Mortality

We identified a range of estimates to quantify the impacts of heath transplants on mortality. One study that finds, for adult heart transplant recipients, that "the median survival time is 9.4 years, in comparison with 2.4 years among patients awaiting a heart."[121] After accounting for timing, this evaluates to a present value of 6.3 life years gained.[122] Another study, which considers the cost effectiveness of treatments for end-stage heart failure, reports average life expectancy for transplant-eligible patients of 1.1 years, and average life expectancy for transplant recipients of 8.5 years,[123] which correspond to a present value of 6.8 life years gained. When analyzing the benefits of this regulatory alternative, we adopt a midpoint estimate of 6.5 life years gained.

e. Impacts of Lung Transplants on Mortality

Compared to other organ transplants considered in this analysis, we anticipate smaller life-expectancy gains for lung transplant recipients. NIH summarizes data for prospective lung transplant candidates, noting that "median survival for single-lung recipients is 4.6 years. The median survival for double-lung recipients is 6.6 years."[124] For analytic simplicity, we adopt a weighted average survival time for single-lung and double-lung transplants of about 6.0, where double-lung transplants account for about 71% of all lung transplants.[125] This matches an

---

[119] Koval, C.E., Farr, M., Krisl, J., Haidar, G., Pereira, M.R., Shrestha, N., Malinis, M.F., Mueller, N.J., Hannan, M.M., Grossi, P. and Huprikar, S., 2019. Heart or lung transplant outcomes in HIV-infected recipients. *The Journal of Heart and Lung Transplantation*, 38(12), pp.1296-1305.

[120] Bentley, T.S. and Ortner, N.J., 2020. 2020 US organ and tissue transplants: Cost estimates, discussion, and emerging issues. Milliman Research Report. https://member.aanlcp.org/wp-content/uploads/2021/03/2020-US-organ-tissue-transplants.pdf. 38/36,677 ≈ 0.1%, where 38 corresponds to estimates for intestine transplants, and 36,677 is the sum of all single-organ transplants.

[121] Rana, A. and Godfrey, E.L., 2019. Outcomes in solid-organ transplantation: success and stagnation. *Texas Heart Institute Journal*, 46(1), pp.75-76.

[122] This study also contains estimates for kidney and liver transplants that evaluate to 6.8 life years gained for kidney transplant recipients and 7.0 life years gained for liver transplant recipients. These estimates are broadly consistent with the values we apply in our analysis of the final rule, 7.5 life years gained for kidney transplants and 6.6 life years gained for liver transplants. In this analysis of alternatives, we maintain the kidney- and liver-specific estimates used in our analysis of the final rule.

[123] Long, E.F., Swain, G.W. and Mangi, A.A., 2014. Comparative survival and cost-effectiveness of advanced therapies for end-stage heart failure. *Circulation: Heart Failure*, 7(3), pp.470-478.

[124] National Institutes of Health, National Heart, Lung, and Blood Institute. "Lung Transplant - What Are the Risks of Lung Transplant? - Risk Factors." https://www.nhlbi.nih.gov/node/3963.

[125] Bentley, T.S. and Ortner, N.J., 2020. 2020 US organ and tissue transplants: Cost estimates, discussion, and emerging issues. Milliman Research Report. https://member.aanlcp.org/wp-content/uploads/2021/03/2020-US-organ-tissue-transplants.pdf. 2,011/(2,011+821) ≈ 71.0%, where 2,011 corresponds to the number of double-lung transplants and 821 corresponds to the number of single-lung transplants.

estimate from one study noting that "median survival for adult lung transplants recipients is approximately 6 years,"[126] and is similar to another study reporting 5.8 years overall, or 6.1 years for a the most recent cohort studied.[127] To account for timing, we assume that these individuals would have a remaining life expectancy of 0.25 years without lung transplantation, and calculate a present value of the average increase in life expectancy per lung transplant recipient of about 5.5 years.

f. Impacts of Pancreas Transplants on Mortality

About 89% of pancreas transplants are performed as combined pancreas-kidney transplants.[128] In our analysis of the final rule, we adopt a simplifying modeling assumption that each transplant recipient receives a single organ. In this analysis, we maintain that assumption and, when assessing the potential benefits of this alternative, we avoid the potential for double counting by not identifying additional health benefits for combined pancreas-kidney transplant recipients. For the small number of pancreas-only transplant recipients, we adopt the estimated life-expectancy gain for kidney transplant recipients of about 7.5 life years.

g. Valuing Mortality Risk Reductions

We follow the same approach as our analysis of the final rule, and monetize the anticipated increases in life expectancy by multiplying the number of life years gained by a VSLY. For transplants occurring in 2024, the estimated life years gained per transplant reported above would be valued at about $3.2 million for heart transplants, $2.7 million for lung transplants, and $3.7 million for pancreas transplants. Consistent with our approach to VSL, we adopt a real growth rate of 1.0% for benefits from transplants occurring in subsequent years. Table 11 reports the annual impacts on heart transplants and the associated benefits and costs under the "All Organs" alternative. Table 12 reports the same impacts for lung transplants, and Table 13 reports the same impacts for pancreas transplants.

h. Costs

Our analysis of the final rule adopts per-transplant cost estimates for livers based on a study that reports average billed charges associated with transplantation.[129] We follow a similar approach and adopt per-transplant costs of $1,959,994 for heart transplants, $1,400,662 for lung transplants, and $481,286 for pancreas transplants for transplants occurring in 2020. For analytic simplicity, we adopt an estimate of the per-transplant costs for lung transplants that is based on a weighted average of the charges for single-lung and double-lung transplants. Double-lung transplants cost about 39% more than single-lung transplants and account for about 71% of all lung transplants. As discussed in the analysis of the final rule, we adopt per-transplant cost

[126] Piechura, L.M., Yazdchi, F., Harloff, M.T., Shim, H., Sharma, N.S., Keshk, M., Coppolino, A., Rinewalt, D.E. and Mallidi, H.R., 2021. Factors Associated with Very Long-Term Survival for Lung Transplant Recipients. *The Journal of Heart and Lung Transplantation*, 40(4), p.S159.
[127] Thabut, G. and Mal, H., 2017. Outcomes after lung transplantation. *Journal of Thoracic Disease*, 9(8), p.2684.
[128] Health Resources and Services Administration. Organ Donation and Transplantation. Analysis of data from 2023. https://data.hrsa.gov/topics/health-systems/organ-donation. 812/(812+101) ≈ 88.9%, where 812 corresponds to the number of kidney-pancreas transplant recipients, and 101 to the number of pancreas transplant recipients.
[129] Bentley, T.S. and Ortner, N.J., 2020. 2020 US organ and tissue transplants: Cost estimates, discussion, and emerging issues. Milliman Research Report. https://member.aanlcp.org/wp-content/uploads/2021/03/2020-US-organ-tissue-transplants.pdf. Cost estimates, originally reported in 2020 dollars inflated to 2023 constant dollars.

estimates for kidneys from another source. Following the same methodology of our analysis of the final rule, we adopt annual real growth rates in the per-transplant costs for heart, lung, and pancreas transplants of 4.5%, 0.9%, and 3.7%, respectively.

Table 11. Economic Impacts Associated with Heart Transplants ($ millions)

Year	Impact on Transplants	Benefits per Transplant	Benefits	Costs per Transplant	Costs
2025	0.0	$3.2	$0.0	$2.4	$0.0
2026	4.0	$3.3	$13.1	$2.5	$10.2
2027	8.0	$3.3	$26.5	$2.7	$21.3
2028	12.0	$3.3	$40.1	$2.8	$33.4
2029	14.7	$3.4	$49.5	$2.9	$42.7
2030	15.7	$3.4	$53.6	$3.0	$47.8
2031	16.0	$3.4	$55.1	$3.2	$50.8
2032	16.0	$3.5	$55.7	$3.3	$53.1
2033	16.0	$3.5	$56.2	$3.5	$55.5
2034	16.0	$3.5	$56.8	$3.6	$58.0
Present Value (2%)	103.9		$356.1		$325.4
Annualized (2%)	11.6		$39.6		$36.2

Table 12. Economic Impacts Associated with Lung Transplants ($ millions)

Year	Impact on Transplants	Benefits per Transplant	Benefits	Costs per Transplant	Costs
2025	0.0	$2.7	$0.0	$1.5	$0.0
2026	2.7	$2.7	$7.4	$1.5	$4.0
2027	5.4	$2.8	$15.0	$1.5	$8.1
2028	8.1	$2.8	$22.7	$1.5	$12.3
2029	9.9	$2.8	$28.0	$1.5	$15.1
2030	10.7	$2.9	$30.4	$1.5	$16.4
2031	10.8	$2.9	$31.2	$1.6	$16.8
2032	10.8	$2.9	$31.5	$1.6	$17.0
2033	10.8	$2.9	$31.8	$1.6	$17.1
2034	10.8	$3.0	$32.2	$1.6	$17.3
Present Value (2%)	70.3		$201.7		$108.6
Annualized (2%)	7.8		$22.5		$12.1

Table 13. Economic Impacts Associated with Pancreas Transplants ($ millions)

Year	Impact on Transplants	Benefits per Transplant	Benefits	Costs per Transplant	Costs
2025	0.0	$3.7	$0.0	$0.6	$0.0
2026	0.1	$3.8	$0.3	$0.6	$0.1
2027	0.2	$3.8	$0.7	$0.6	$0.1
2028	0.3	$3.8	$1.0	$0.6	$0.2
2029	0.3	$3.9	$1.3	$0.7	$0.2
2030	0.4	$3.9	$1.4	$0.7	$0.2
2031	0.4	$4.0	$1.4	$0.7	$0.3
2032	0.4	$4.0	$1.4	$0.7	$0.3
2033	0.4	$4.0	$1.5	$0.8	$0.3
2034	0.4	$4.1	$1.5	$0.8	$0.3
Present Value (2%)	2.4		$9.3		$1.7
Annualized (2%)	0.3		$1.0		$0.2

4. Summary and Comparison of Regulatory Alternatives

Table 14 summarizes the economic impacts associated with the final rule and three regulatory alternatives. We report benefits, costs, and transfers against a common baseline scenario discussed in Section II.C and extended with respect to hearts, lungs, and pancreases in this section. Across all alternatives, we anticipate similar costs associated with transplant centers reading and understanding the final rule, reviewing policies and procedures, and training staff as with the final rule, and incorporate these costs, presented above in Table 8 into the economic impacts reported in Table 14.

Table 14. Annualized Economic Impacts: Final Rule and Alternatives ($ millions)

Impact	Final Rule	Kidneys Only	Livers Only	All Organs
Benefits	$612	$359	$253	$676
Costs	$83	$2	$81	$132
Transfers	$30	$30	$0	$30
Net Benefits	$529	$358	$172	$544

In addition to the economic impacts that we quantify and monetize in this analysis, the final rule and regulatory alternatives would forgo some information and data that would be gathered from research and trials occurring under the baseline scenario. We discuss this effect in our analysis of the final rule and note that this will also result in reductions in the time spent analyzing data and similar activities. We are not able to monetize the value of this forgone information, data, and analysis for any organ; however, at this time, we have collected more evidence on kidney and liver transplants. As noted in the baseline section, 519 organs have been transplanted between donors with HIV and patients with HIV, including 419 kidneys, 97 livers, 3 hearts, and no other

organs. At this time, the data available to us make it difficult to fully assess the safety and outcomes of HOPE Act transplants for organs other than kidney and liver.

H. Uncertainty and Sensitivity Analysis

1. Monte Carlo Simulation

We run a Monte Carlo simulation to compute the primary, low, and high estimates for many of the outcomes reported in this analysis.[130] Table 15 summarizes the probability distributions for the parameters of the simulation that we model with uncertainty. We discuss the sources for the range of values for the first two parameters in Section II.C, the next four parameters in Section II.D, and the last two parameters in Section II.E.

For each trial of the simulation, we sample one random value for each of the eight parameters. Next, we repeat the full analysis described in Sections II.C through II.F, except using the set of randomly drawn parameters instead of the primary estimates used in those sections, then storing the critical intermediate and final calculations for each trial. We repeat this simulation for 30,000 trials, and report the primary, low, and high that correspond to the mean, 5th percentile, and 95th percentile of the simulated outcomes.

Table 15. Parameters Modeled with Uncertainty

Parameter	Distribution	Min	Max	Mode	Std. Dev	Mean
Baseline Transplants, Kidney	Normal	N/A	N/A	60.42	2.81	60.42
Baseline Transplants, Liver	Normal	N/A	N/A	11.46	1.48	11.46
Donation Consent Rate	Triangle	0.69	0.80	0.75	0.02	0.75
Living Donor Multiplier, Kidney	Triangle	1.00	1.33	1.01	0.08	1.11
Living Donor Multiplier, Liver	Triangle	1.00	1.06	1.00	0.01	1.02
Yearly Phase-in of Impacts	Uniform	0.17	0.33	N/A	0.05	0.25
Quality-of-life Gain, Kidney	Normal	N/A	N/A	0.11	0.02	0.11
Value per Statistical Life, 2024	Triangle	$6.1	$19.9	$13.2	$2.82	$13.1

Note: value per statistical life reported in millions of constant 2023 dollars

Table 16 reports the impacts associated with kidney transplants, including the health benefits, time benefits, and costs for each year of the analysis. Table 17 reports the yearly impacts associated with liver transplants. Table 18 reports the yearly benefits, costs, transfers, and net benefits, and Table 19 reports the present value and annualized impacts for the 10-year time horizon of the analysis.

[130] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2021. "Addressing Uncertainty in Regulatory Impact Analysis." https://aspe.hhs.gov/reports/uncertainty-rias.

Table 16. Yearly Impacts Associated with Kidney Transplants ($ millions)

	Mean	p5	p95
2025			
Impact on Transplants, Kidneys	0	0	0.000
Health Benefits, Kidneys	0	0	0.000
Time Benefits, Kidneys	0	0	0.000
Costs, Kidneys	0	0	0.000
2026			
Impact on Transplants, Kidneys	26.35	17.284	37.006
Health Benefits, Kidneys	115.777	62.577	182.967
Time Benefits, Kidneys	3.208	2.104	4.505
Costs, Kidneys	.517	.339	0.726
2027			
Impact on Transplants, Kidneys	52.7	34.569	74.011
Health Benefits, Kidneys	233.869	126.406	369.594
Time Benefits, Kidneys	6.416	4.208	9.010
Costs, Kidneys	1.038	.681	1.457
2028			
Impact on Transplants, Kidneys	79.049	51.853	111.017
Health Benefits, Kidneys	354.312	191.504	559.935
Time Benefits, Kidneys	9.623	6.313	13.515
Costs, Kidneys	1.562	1.025	2.193
2029			
Impact on Transplants, Kidneys	96.568	69.115	124.632
Health Benefits, Kidneys	437.266	252.372	653.201
Time Benefits, Kidneys	11.756	8.414	15.173
Costs, Kidneys	1.915	1.37	2.471
2030			
Impact on Transplants, Kidneys	103.55	83.63	127.821
Health Benefits, Kidneys	473.624	285.354	684.909
Time Benefits, Kidneys	12.606	10.181	15.561
Costs, Kidneys	2.06	1.664	2.543
2031			
Impact on Transplants, Kidneys	105.282	86.538	128.906
Health Benefits, Kidneys	486.408	294.914	700.317
Time Benefits, Kidneys	12.817	10.535	15.693
Costs, Kidneys	2.102	1.727	2.573
2032			
Impact on Transplants, Kidneys	105.282	86.538	128.906
Health Benefits, Kidneys	491.272	297.863	707.320
Time Benefits, Kidneys	12.817	10.535	15.693
Costs, Kidneys	2.109	1.733	2.582
2033			
Impact on Transplants, Kidneys	105.282	86.538	128.906
Health Benefits, Kidneys	496.185	300.842	714.393
Time Benefits, Kidneys	12.817	10.535	15.693
Costs, Kidneys	2.116	1.739	2.591
2034			
Impact on Transplants, Kidneys	105.282	86.538	128.906
Health Benefits, Kidneys	501.147	303.85	721.537
Time Benefits, Kidneys	12.817	10.535	15.693
Costs, Kidneys	2.123	1.745	2.600

Notes: benefits and costs are reported in millions of constant 2023 dollars; p5 and p95 correspond to the 5% and 95% percentiles across simulation results.

Table 17. Yearly Impacts Associated with Liver Transplants ($ millions)

	Mean	p5	p95
2025			
Impact on Liver Transplants	0	0	0.000
Health Benefits, Livers	0	0	0.000
Costs, Livers	0	0	0.000
2026			
Impact on Liver Transplants	25.105	17.491	32.944
Health Benefits, Livers	83.87	47.088	128.074
Costs, Livers	27.219	18.964	35.718
2027			
Impact on Liver Transplants	50.21	34.982	65.888
Health Benefits, Livers	169.418	95.117	258.709
Costs, Livers	54.869	38.228	72.002
2028			
Impact on Liver Transplants	75.315	52.474	98.832
Health Benefits, Livers	256.668	144.102	391.944
Costs, Livers	82.954	57.796	108.857
2029			
Impact on Liver Transplants	92.015	69.965	105.777
Health Benefits, Livers	316.796	190.371	452.030
Costs, Livers	102.15	77.671	117.427
2030			
Impact on Liver Transplants	98.675	87.383	106.725
Health Benefits, Livers	343.159	216.448	471.149
Costs, Livers	110.41	97.775	119.418
2031			
Impact on Liver Transplants	100.328	93.353	107.120
Health Benefits, Livers	352.433	223.155	481.296
Cots, Livers	113.148	105.282	120.808
2032			
Impact on Liver Transplants	100.328	93.353	107.120
Health Benefits, Livers	355.957	225.386	486.109
Costs, Livers	114.043	106.114	121.763
2033			
Impact on Liver Transplants	100.328	93.353	107.120
Health Benefits, Livers	359.517	227.64	490.970
Costs, Livers	114.945	106.954	122.727
2034			
Impact on Liver Transplants	100.328	93.353	107.120
Health Benefits, Livers	363.112	229.916	495.880
Costs, Livers	115.854	107.8	123.697

Notes: benefits and costs are reported in millions of constant 2023 dollars; p5 and p95 correspond to the 5% and 95% percentiles across simulation results.

Table 18. Yearly Monetized Impacts ($ millions)

	Mean	p5	p95
2025			
Benefits	0	0	0.000
Costs	.515	.515	0.515
Transfers	0	0	0.000
Net Benefits	-.515	-.515	-0.515
2026			
Benefits	202.855	113.194	312.451
Costs	27.736	19.323	36.385
Transfers	10.113	6.634	14.203
Net Benefits	175.119	90.56	278.840
2027			
Benefits	409.703	228.606	631.076
Costs	55.906	38.948	73.340
Transfers	20.296	13.313	28.503
Net Benefits	353.797	182.971	563.322
2028			
Benefits	620.604	346.271	955.969
Costs	84.516	58.879	110.871
Transfers	30.548	20.039	42.902
Net Benefits	536.088	277.264	853.531
2029			
Benefits	765.819	457.775	1107.210
Costs	104.065	79.12	119.628
Transfers	37.447	26.801	48.329
Net Benefits	661.754	361.925	994.109
2030			
Benefits	829.389	519.011	1154.807
Costs	112.47	99.565	121.637
Transfers	40.292	32.541	49.736
Net Benefits	716.92	407.587	1039.150
2031			
Benefits	851.658	535.227	1179.727
Costs	115.249	107.203	123.047
Transfers	41.107	33.788	50.331
Net Benefits	736.409	420.964	1062.480
2032			
Benefits	860.047	540.465	1191.404
Costs	116.152	108.042	124.012
Transfers	41.248	33.905	50.504
Net Benefits	743.895	425.303	1073.214
2033			
Benefits	868.519	545.756	1203.196
Costs	117.061	108.889	124.984
Transfers	41.39	34.021	50.678
Net Benefits	751.458	429.687	1084.067
2034			
Benefits	877.076	551.1	1215.094
Costs	117.977	109.742	125.964
Transfers	41.532	34.138	50.852
Net Benefits	759.099	434.117	1095.032

Notes: benefits, costs, transfers, and net benefits are reported in millions of constant 2023 dollars; p5 and p95 correspond to the 5% and 95% percentiles across simulation results.

Table 19. Present Value and Annualized Impacts ($ millions)

	Mean	p5	p95
Present Value of Benefits	5506.198	3425.933	7707.295
Health Benefits, Kidneys	3144.644	1888.408	4562.699
Health Benefits, Livers	2278.356	1426.745	3145.634
Time-Saving Benefits	83.197	66.123	103.818
Present Value of Costs	746.25	654.918	829.109
Present Value of Transfers	266.458	211.891	332.391
Present Value of Net Benefits	4759.948	2702.999	6935.356
Annualized Benefits	612.986	381.397	858.026
Health Benefits, Kidneys	350.082	210.23	507.949
Health Benefits, Livers	253.641	158.835	350.193
Time-Saving Benefits	9.262	7.361	11.558
Annualized Costs	83.077	72.91	92.302
Annualized Transfers	29.664	23.589	37.004
Annualized Net Benefits	529.908	300.916	772.089

Notes: benefits, costs, transfers, and net benefits are reported in millions of constant 2023 dollars; p5 and p95 correspond to the 5% and 95% percentiles across simulation results; all present value and annualization calculations adopt a constant 2% real discount rate.

2. Alternative Estimates of Transplants under the Final Rule

In our main analysis, we adopt annual projections of organs from deceased donors with HIV potentially available for transplants of 200 kidneys and 147 livers, corresponding to estimated counts of lower-risk organs reported in Woods et al. (2022). After accounting for several adjustments to these estimates and subtracting transplants occurring under the baseline scenario, we reported that the final rule will result in an additional 105 kidney and 100 liver transplants per year once the policy effects fully materialize. This sensitivity analysis presents similar calculations based on alternative estimates from the studies discussed in Section II.D. We consider estimates from Boyarsky et al. (2011), Richterman et al. (2015), the higher estimates reported in Woods et al. (2022), and our primary estimates reported in the preliminary RIA for comparison. Table 20 summarizes the number of kidney and liver transplants under the final rule, with and without adjustments, and also reports the impact on transplants by subtracting those occurring under a common baseline scenario described in Section II.C.

Table 20. Alternative Estimates of the Annual Impacts on Transplants

Source	No Adjustments		With Adjustments		Impact	
	Kidneys	Livers	Kidneys	Livers	Kidneys	Livers
Woods et al. (2022) Low-Risk Estimate	200	147	166	112	105	100
Woods et al. (2022) Higher Estimate	792	433	656	329	596	318
Boyarsky et al. (2011)	435	471	361	358	300	347
Richertman et al. (2015)	192	247	159	188	99	176
Preliminary RIA	N/A	N/A	N/A	N/A	100	177

Section II.E of the main analysis describes our approach to quantifying and monetizing the health benefits associated with kidney and liver transplants and time-saving benefits associated

with fewer kidney dialysis treatments, and Section II.F describes our approach to quantifying and monetizing costs and transfers associated with transplantation. Following the same approach, Table 21 reports the annual benefits, costs, transfers, and net benefits for impacts occurring in 2031, the first year we anticipate the full impacts on transplants will occur.

Table 21. Alternative Estimates of Annual Economic Impacts, 2031 ($ millions)

Source	Benefits	Costs	Transfers	Net Benefits
Woods et al. (2022) Low-Risk Estimate	$851	$115	$41	$736
Woods et al. (2022) Higher Estimate	$3,939	$370	$233	$3,568
Boyarsky et al. (2011)	$2,639	$397	$117	$2,242
Richertman et al. (2015)	$1,086	$201	$39	$886
Preliminary RIA	$1,096	$202	$39	$894

3. Alternative Estimates of the Cost per Kidney Transplant

In our main analysis, we adopt an estimate of the cost per kidney transplant from a study that compared costs associated with kidney transplantations to costs associated with kidney dialysis. After adjusting for inflation and accounting for timing of these costs through discounting, these differences amounted to a $18,961 net increase in medical expenditures over 10 years. Table 6 in the main analysis reports primary estimates of the impacts on kidney transplants and the costs and transfers associated with those transplants. In this section, we consider two alternative estimates for the change in medical expenditures per kidney transplant.

First, we derive an estimate from supplementary digital content of the study we apply in our main analysis. In this supplementary digital content, the authors reported comparable cost estimates covering a longer time horizon. Over 20 years, they find that patients on dialysis incur expenses of $607,914, while patients receiving donor organs incur expenses of $537,912.[131] These estimates indicate that switching from dialysis will result in a present value of $70,002 in cost savings per kidney transplant.

Second, we adopt an estimate from a separate cost analysis that compares the annual cost of dialysis with the initial cost per transplant and annual cost of immunosuppressant drugs. Over a ten-year period, their analysis indicates a present value of $472,143 in cost savings per transplant.[132]

[131] Axelrod D.A., Schnitzler M.A., Xiao H., et al. 2018. "An Economic Assessment of Contemporary Kidney Transplant Practice." *American Journal of Transplantation*, 18: 1168-1176. Supplemental Digital Content. https://www.amjtransplant.org/cms/10.1111/ajt.14702/attachment/e0014928-d2d8-4d5a-972b-0c337839a685/mmc1-sup1-tables1-s2.pdf. Table S2: Primary Results with 20-year time horizon. Original estimates reported in 2016 dollars inflated to 2023 constant dollars.

[132] Brannon, I. (2023). Saving lives while saving money: The Living Kidney Donor Support Act. *Regulation*, 46(2), 32-37. https://www.cato.org/regulation/summer-2023/saving-lives-while-saving-money#budgetary-effects. Table 1. Annual Costs per Patient over 10 Years. Original estimates reported in 2022 dollars inflated to 2023 constant dollars and reported as a present value using a 2 percent real discount rate.

Using these estimates, we compare the annual costs or cost savings associated with kidney transplants occurring in 2031, the first year we anticipate the full impacts on transplants will occur. Accounting for the annual real growth rate, our primary estimate from our main analysis is $19,962 per kidney transplant; and our two alternative estimates are -$73,699 and -$486,951, where the negative costs correspond to positive cost savings. In 2031, when we anticipate an additional 105 kidney transplants attributable to the final rule, our primary estimate of the costs associated with kidney transplantation is $2.0 million. Under the alternative estimates, the cost savings in the same year would be $7.8 million or $51.3 million.

I. Distributional Effects

Section II.E of this RIA discusses and monetizes benefits related to incremental changes in the number of kidney and liver transplants performed annually. These impacts include health benefits associated with increases in life expectancy for organ transplant recipients and, for kidney transplant recipients, benefits associated with improved quality-of-life and time savings from fewer kidney dialysis visits. We noted that these benefits will be realized by recipients living with HIV receiving organs from donors with HIV as a direct result of the final rule, but also by recipients without HIV receiving organs from donors without HIV through reduced waiting times.

Section D of the final rule's preamble provides information on the individuals in need of transplants and speaks to some of the population groups that are the most likely to be affected by the final rule. That discussion includes references to several current and historic barriers to transplantation that differ by population group, statistics identifying differences in demographic characteristics for individuals with end-stage diseases, and information on the disproportionate impact of HIV by race, ethnicity, and socioeconomic status.

J. International Effects

We do not anticipate any international effects associated with the final rule.

III. **Final Small Entity Analysis**

The Regulatory Flexibility Act (RFA) "requires agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment. The RFA applies to a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions."[133] This analysis, as well as other sections in this document and the preamble of the final rule, serves as the final regulatory flexibility analysis (FRFA).

On September 12, 2024, HHS published an NPRM[134] and preliminary RIA[135] containing an initial regulatory flexibility analysis (IRFA) of the proposed rule. The IRFA considered the impact of the proposed rule on small entities and determined that the impacts of the proposed rule would be small relative to the number of organ transplants performed annually, and that the costs of the proposed rule would be small relative to the annual payroll of firms in the smallest enterprise size category. HHS certified that the proposed rule would not have a significant economic impact on a substantial number of small entities, and requested comment on all aspects of the NPRM and RIA.

We did not receive any comments addressing HHS's certification of the proposed rule or the IRFA. Thus, when considering the impact of the final rule on small entities, we adopted the general analytic approach of the IRFA to develop a FRFA. We reviewed the sources of data referenced in the IRFA, updated these sources when newer data were available, and updated all estimates to match revisions described in other sections of the RIA. We also extended the analysis to consider the beneficial economic impacts of the final rule on small entities. This FRFA confirms the general findings of the IRFA: the impacts of the final rule on kidney and liver transplants are small relative to the number of transplants performed annually, and the economic impacts of the final rule on affected small entities are small relative to the average payroll of firms in the smallest enterprise size category. Thus, this FRFA concludes, and HHS certifies, that the final rule will not have a significant economic impact on a substantial number of small entities.

A. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) maintains a Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) codes.[136] We replicate the SBA's description of this table:

---

[133] U.S. Small Business Administration, Office of Advocacy. August 31, 2017. "A Guide For Government Agencies: How To Comply With The Regulatory Flexibility Act." https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/. Page 1.

[134] Office of the Assistant Secretary for Health and Health Resources and Services Administration. September 12, 2024. "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act" notice of proposed rulemaking. Federal Register. 89 FR 74174.

[135] Office of the Assistant Secretary for Planning and Evaluation. September 12, 2024. "Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act" Preliminary Regulatory Impact Analysis. Regulations.gov Docket (HRSA-2024-0001). Document ID HRSA-2024-0001-0001.

[136] U.S. Small Business Administration (2023). "Table of Size Standards." March 17, 2023 Dhttps://www.sba.gov/document/support--table-size-standards.

This table lists small business size standards matched to industries described in the North American Industry Classification System (NAICS), as modified by the Office of Management and Budget, effective January 1, 2022.

The size standards are for the most part expressed in either millions of dollars (those preceded by "$") or number of employees (those without the "$"). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm. How to calculate average annual receipts and average employment of a firm can be found in 13 CFR § 121.104 and 13 CFR § 121.106, respectively.

The final rule will likely affect kidney dialysis centers and transplant centers. In this section of the FRFA, we provide a description and number of affected small entities, including information about annual payroll per firm by enterprise size category.

1. Affected Kidney Dialysis Centers that are Small Entities

The final rule will likely affect entities in NAICS category 621492, Kidney Dialysis Centers, which has a size standard of $47.0 million. We compared this size standard to the average payroll for firms in this NAICS category.[137] We conclude, based on the average payroll per firm in the enterprise size categories, that firms with fewer than 500 employees, which make up about 92% of all firms in this NAICS category, are likely to be small entities, while 8% of firms with more than 500 employees are unlikely to be small entities under the size standard. Table 22 presents statistics for kidney dialysis centers by enterprise size, including the annual payroll per firm.

Table 22. Statistics for Kidney Dialysis Centers by Enterprise Size

Enterprise Size	Firms	Employment	Annual Payroll ($1,000)	Annual Payroll per Firm
01: Total	507	131,953	$8,585,278	$16,933,488
02: <5 employees	160	264	$33,439	$208,993
03: 5-9 employees	70	490	$32,860	$469,425
04: 10-19 employees	87	1,240	$76,124	$874,992
05: <20 employees	317	1,994	$142,423	$449,284
06: 20-99 employees	125	4,550	$275,886	$2,207,087
07: 100-499 employees	26	4,022	$317,627	$12,216,417
08: <500 employees	468	10,566	$735,936	$1,572,512
09: 500+ employees	39	121,387	$7,849,343	$201,265,194

[137] U.S. Census Bureau. December 2023. "2021 SUSB Annual Data Tables by Establishment Industry." https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html. Annual payroll estimates originally reported in 2021 dollars inflated to 2023 constant dollars.

2. Affected Transplant Centers that are Small Entities

The final rule will also likely affect the 248 transplant centers identified in Section II.C of this RIA. These transplant centers are hospitals, medical centers, or health systems, and likely classified in NAICS category 622110, general medical and surgical hospitals, which has a size standard of $47 million. We compared this size standard to the annual payroll for firms in this NAICS category.[138] We conclude, based on the annual payroll per firm in the enterprise size categories, that almost all transplant centers with fewer than 500 employees are likely to be small entities. Further, while the average payroll per firm in the largest enterprise size category is approximately 8 times the size standard, many of these transplant centers are likely small entities due to not-for-profit status. Table 23 presents statistics for general medical and surgical hospitals by enterprise size, including the annual payroll per firm.

Table 23. Statistics for General Medical and Surgical Hospitals by Enterprise Size

Enterprise Size	Firms	Employment	Annual Payroll ($1,000)	Annual Payroll per Firm
01: Total	2,542	5,577,400	$451,900,620	$177,773,651
02: <5 employees	215	238	$67,950	$316,049
03: 5-9 employees	17	109	$14,597	$858,644
04: 10-19 employees	12	146	$7,909	$659,043
05: <20 employees	244	493	$90,456	$370,721
06: 20-99 employees	185	12,431	$703,601	$3,803,249
07: 100-499 employees	962	227,376	$14,303,594	$14,868,601
08: <500 employees	1,391	240,300	$15,097,651	$10,853,811
09: 500+ employees	1,151	5,337,100	$436,802,970	$379,498,670

B. Description of the Impacts of the Final Rule on Small Entities

1. Impacts on Kidney Dialysis Centers

In 2021, the prevalent count of individuals receiving in-center hemodialysis was 462,539.[139] We estimate that the final rule will reduce the number of individuals receiving dialysis by about 105 per year. This impact represents a change of about 0.02% of all dialysis patients[140] and will likely have a similar impact, measured as a proportion of revenue, for affected kidney dialysis centers that are small entities. As one example calculation, a 0.02% reduction in revenue for an affected kidney dialysis center with $208,993 in annual revenue, which corresponds to the

[138] U.S. Census Bureau. December 2023. "2021 SUSB Annual Data Tables by Establishment Industry." https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html. Annual payroll estimates originally reported in 2021 dollars inflated to 2023 constant dollars.
[139] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. October 31, 2023. United States Renal Data System 2023 Annual Data Report. End Stage Rental Disease, Chapter 1. Figure 1.6 Prevalent ESRD by modality, 2001-2021. https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities.
[140] 105 / 462,539 * 100 ≈ 0.023.

annual payroll per firm for kidney dialysis centers with fewer than 5 employees, would be an economic impact of about $48 per year.

In the context of the RFA, HHS generally considers a final rule to have a significant impact on a substantial number of small entities if it has at least a 3% impact on revenue on at least 5% of small entities. The impact on the total number of individuals receiving dialysis is far below the 3% threshold; therefore, this analysis concludes that the final rule will not have a significant economic impact on a substantial number of kidney dialysis centers that are small entities.

2. Impacts on Transplant Centers

Section II.F of this RIA identifies costs to transplant centers associated with reading and understanding the final rule, reviewing policies and procedures, and training staff. Across transplant centers of all sizes, we estimate these costs will amount to an average of $4,891 in per firm. We next compare this average cost to the average payroll of firms in the smallest enterprise size reported in Table 23. General medical and surgical hospitals with fewer than 5 employees have an annual payroll per firm of $316,049. The average cost per transplant center is about 1.5% of this annual payroll; however, we expect that most, if not all, transplant centers fall into larger enterprise size categories, and thus the average cost per firm would represent a smaller share of annual payroll.

We also considered the benefits of the final rule on transplant centers. When the effects of the final rule fully materialize, the additional 105 kidney and 100 liver transplants will represent an increase in the total number of kidney transplants by about 0.4% and an increase in the total number of liver transplants by about 0.9%. The final rule will likely have a similar impact, measured as a proportion of revenue, for transplant centers. These impacts on transplants would represent a small additional source of revenue for transplant centers, which would likely offset some or all of the incremental costs incurred under the final rule. When considering the benefits, costs, and overall economic impact on transplant centers that are small entities, these impacts are below the 3% impact on revenue threshold for a significant impact, even for firms in the smallest enterprise size category. Therefore, this analysis concludes that the final rule will not have a significant economic impact on a substantial number of transplant centers that are small entities.

IV. **References**

Axelrod D.A., Schnitzler M.A., Xiao H., et al. 2018. "An Economic Assessment of Contemporary Kidney Transplant Practice." *American Journal of Transplantation*, 18: 1168-1176.

Bentley, T.S. and Ortner, N.J., 2020. 2020 US organ and tissue transplants: Cost estimates, discussion, and emerging issues. Milliman Research Report. https://member.aanlcp.org/wp-content/uploads/2021/03/2020-US-organ-tissue-transplants.pdf.

Botha, J., Fabian, J., Etheredge, H., Conradie, F. and Tiemessen, C.T., 2019. HIV and solid organ transplantation: where are we now. *Current HIV/AIDS Reports*, 16, pp.404-413.

Boyarsky, B.J., Hall, E.C., Singer, A.L., Montgomery, R.A., Gebo, K.A. and Segev, D.L., 2011. Estimating the potential pool of HIV-infected deceased organ donors in the United States. *American Journal of Transplantation*, 11(6), pp.1209-1217.

Brannon, I. (2023). Saving lives while saving money: The Living Kidney Donor Support Act. *Regulation*, 46(2), 32-37. https://www.cato.org/regulation/summer-2023/saving-lives-while-saving-money.

Durand, C.M., Florman, S., Motter, J.D., Brown, D., Ostrander, D., Yu, S., Liang, T., Werbel, W.A., Cameron, A., Ottmann, S. and Hamilton, J.P., 2022. HOPE in action: a prospective multicenter pilot study of liver transplantation from donors with HIV to recipients with HIV. *American Journal of Transplantation*, 22(3), pp.853-864.

Durand, C.M., Halpern, S.E., Bowring, M.G., Bismut, G.A., Kusemiju, O.T., Doby, B., Fernandez, R.E., Kirby, C.S., Ostrander, D., Stock, P.G., Mehta, S., Turgeon, N.A., Wojciechowski, D., Huprikar, S., Florman, S., Ottmann, S., Desai, N.M., Cameron, A., Massie, A.B., Tobian, A.A.R., Redd, A.D., Segev, D.L. (2018). Organs from deceased donors with false-positive HIV screening tests: An unexpected benefit of the HOPE act. American Journal of *Transplantation*, 18(10), 2579–2586. https://doi.org/10.1111/ajt.14993.

Durand, C.M., Martinez, N., Neumann, K., Benedict, R.C., Baker, A.W., Wolfe, C.R., Stosor, V., Shetty, A., Dietch, Z.C., Goudy, L. and Callegari, M.A., 2023. Living kidney donors with HIV: experience and outcomes from a case series by the HOPE in Action Consortium. *The Lancet Regional Health–Americas*, 24.

Durand, C.M., Massie, A., Florman, S., Liang, T., Rana, M.M., Friedman-Moraco, R., Gilbert, A., Stock, P., Mehta, S.A., Mehta, S. and Stosor, V., 2024. Safety of Kidney Transplantation from Donors with HIV. *New England Journal of Medicine*, 391(15), pp.1390-1401.

Durand, C.M., Zhang, W., Brown, D.M., Yu, S., Desai, N., Redd, A.D., Bagnasco, S.M., Naqvi, F.F., Seaman, S., Doby, B.L. and Ostrander, D., 2021. A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action. *American Journal of Transplantation*, 21(5), pp.1754-1764.

Girgenti, R., Tropea, A., Buttafarro, M.A., Ragusa, R. and Ammirata, M., 2020. Quality of life in liver transplant recipients: a retrospective study. *International Journal of Environmental Research and Public Health*, 17(11), p.3809.

Goldberg, D.S., Halpern, S.D. and Reese, P.P., 2013. Deceased organ donation consent rates among racial and ethnic minorities and older potential donors. *Critical Care Medicine*, 41(2), p.496.

Hariharan, S., Israni, A.K. and Danovitch, G., 2021. Long-term survival after kidney transplantation. *New England Journal of Medicine*, 385(8), pp.729-743.

Huang, E., Thakur, N., and Meltzer, D. 2008. "The Cost-Effectiveness of Renal Transplantation," When Altruism Isn't Enough, edited by Sally Satel. AEI Press. https://www.aei.org/wp-content/uploads/2014/07/-when-altruism-isnt-enough_161836373082.pdf.

Israni, A.K., Zaun, D.A., Gauntt, K., Schaffhausen, C.R., Lozano, C., McKinney, W.T., Miller, J.M. and Snyder, J.J., 2024. OPTN/SRTR 2022 Annual Data Report: Deceased Organ Donation. *American Journal of Transplantation*, 24(2), pp.S457-488.

Kearsley, A. "HHS Standard Values for Regulatory Analysis, 2024." Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. January 2024. https://aspe.hhs.gov/reports/standard-ria-values.

Koval, C.E., Farr, M., Krisl, J., Haidar, G., Pereira, M.R., Shrestha, N., Malinis, M.F., Mueller, N.J., Hannan, M.M., Grossi, P. and Huprikar, S., 2019. Heart or lung transplant outcomes in HIV-infected recipients. *The Journal of Heart and Lung Transplantation*, 38(12), pp.1296-1305.

Locke, J.E., Gustafson, S., Mehta, S., Reed, R.D., Shelton, B., MacLennan, P.A., Durand, C., Snyder, J., Salkowski, N., Massie, A. and Sawinski, D., 2017. "Survival benefit of kidney transplantation in HIV-infected patients." *Annals of Surgery*, 265(3), pp.604-608.

Long, E.F., Swain, G.W. and Mangi, A.A., 2014. Comparative survival and cost-effectiveness of advanced therapies for end-stage heart failure. *Circulation: Heart Failure*, 7(3), pp.470-478.

Luo, X., Leanza, J., Massie, A.B., Garonzik-Wang, J.M., Haugen, C.E., Gentry, S.E., Ottmann, S.E. and Segev, D.L., 2018. MELD as a metric for survival benefit of liver transplantation. *American Journal of Transplantation*, 18(5), pp.1231-1237.

Lushniak, S.A. and Durand, C.M., 2022. Donors with human immunodeficiency virus and hepatitis C virus for solid organ transplantation: what's new. *Current Opinion in Infectious Diseases*, 35(4), pp.321-329.

Lynch, E.N. and Russo, F.P., 2023. Liver Transplantation in People Living with HIV: Still an Experimental Procedure or Standard of Care? *Life*, 13(10), p.1975.

Mayer, C., Agbobli-Nuwoaty, S.E., Li, J., Carlson, K., Pallela, F.J., Durham, M.D. and Buchacz, K., 2022. Unmet Need for Solid Organ Transplantation among People with HIV and End Stage Kidney or Liver Disease: a Brief Report from the HIV Outpatient Study, 2009-2023. *Journal of Acquired Immune Deficiency Syndromes*, pp.10-1097.

Motter, J.D., Hussain, S., Brown, D.M., Florman, S., Rana, M.M., Friedman-Moraco, R., Gilbert, A.J., Stock, P., Mehta, S., Mehta, S.A., Stosor, V., et al. 2023. Wait Time Advantage for Transplant Candidates With HIV Who Accept Kidneys From Donors With HIV Under the HOPE Act. *Transplantation*, pp.10-1097.

Nambiar, P.H., Doby, B., Tobian, A.A., Segev, D.L. and Durand, C.M., 2021. Increasing the donor pool: organ transplantation from donors with HIV to recipients with HIV. *Annual Review of Medicine*, 72(1), pp.107-118.

Nguyen, A.Q., Anjum, S.K., Halpern, S.E., Kumar, K., Rasmussen, S.E.V.P., Doby, B., Shaffer, A.A., Massie, A.B., Tobian, A.A., Segev, D.L. and Sugarman, J., 2018. Willingness to donate organs among people living with HIV. *Journal of Acquired Immune Deficiency Syndromes*, 79(1), pp.e30-e36.

Nickel, M., Rideout, W., Shah, N., Reintjes, F., Chen, J.Z., Burrell, R. and Pauly, R.P., 2017. Estimating patient-borne water and electricity costs in home hemodialysis: a simulation. *Canadian Medical Association Open Access Journal*, 5(1), pp.E61-E65. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378499/.

Piechura, L.M., Yazdchi, F., Harloff, M.T., Shim, H., Sharma, N.S., Keshk, M., Coppolino, A., Rinewalt, D.E. and Mallidi, H.R., 2021. Factors Associated with Very Long-Term Survival for Lung Transplant Recipients. *The Journal of Heart and Lung Transplantation*, 40(4), p.S159.

Rana, A. and Godfrey, E.L., 2019. Outcomes in solid-organ transplantation: success and stagnation. *Texas Heart Institute Journal*, 46(1), pp.75-76.

Richterman, A., Sawinski, D., Reese, P.P., Lee, D.H., Clauss, H., Hasz, R.D., Thomasson, A., Goldberg, D.S., Abt, P.L., Forde, K.A., Bloom, R.D., Doll, S.L., Brady, K.A., and Blumberg, E.A. 2015. An assessment of HIV-infected patients dying in care for deceased organ donation in a United States urban center. *American Journal of Transplantation*, 15(8), pp.2105-2116.

Robinson, L.A. and Hammitt, J.K., 2016. "Valuing reductions in fatal illness risks: Implications of recent research." *Health Economics*, 25(8), pp. 1039-1052.

Shelton, B.A., MacLennan, P.A., Becker, D.J., Sen, B., Budhwani, H. and Locke, J.E., 2023. Access to the kidney transplant waitlist for people with HIV. *Transplantation*, 107(5), pp.e156-e157.

Shelton, B.A., Sen, B., Becker, D.J., MacLennan, P.A., Budhwani, H. and Locke, J.E., 2024. Quantifying the association of individual-level characteristics with disparities in kidney transplant waitlist addition among people with HIV. *AIDS*, 38(5), pp.731-737.

Siminoff, L.A., Agyemang, A.A. and Traino, H.M., 2013. Consent to organ donation: a review. *Progress in Transplantation*, 23(1), pp.99-104.Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S. and Gill, J., 2011. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American Journal of Transplantation*, 11(10), pp.2093-2109.

Thabut, G. and Mal, H., 2017. Outcomes after lung transplantation. *Journal of Thoracic Disease*, 9(8), p.2684.

Thornton, J., 2021. Expanding HIV-positive organ donation. *The Lancet*, 397(10270), pp.184-185.

Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S. and Gill, J., 2011. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American Journal of Transplantation*, 11(10), pp.2093-2109.

VanDerwerken, D.N., Wood, N.L., Segev, D.L. and Gentry, S.E., 2021. The precise relationship between model for end-stage liver disease and survival without a liver transplant. *Hepatology*, 74(2), pp.950-960.

Velázquez, A. F., Thorsness, R., Trivedi, A. N., & Nguyen, K. H., 2022. "County-Level Dialysis Facility Supply and Distance Traveled to Facilities among Incident Kidney Failure Patients." *Kidney360*, 3(8), pp.1367–1373. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9416828/.

Vernadakis, S., Paul, A., Gercken, G. and Sotiropoulos, G., 2014. Liver Transplantation for MELD-Score 40 Patients: Preliminary Results and Single Center Experience.: Abstract# B1097. *Transplantation*, 98, p.729.Wolfe, R.A., Ashby, V.B., Milford, E.L., Ojo, A.O., Ettenger, R.E., Agodoa, L.Y., Held, P.J. and Port, F.K., 1999. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. *New England Journal of Medicine*, 341(23), pp.1725-1730.

Woods, C., Owens, G., Shelton, B.A., MacLennan, P.A., Sawinski, D., Jacobson, J. and Locke, J.E., 2022. Efficacy of hope: Analysis of organ quality and availability among deceased HIV-positive donors. *Transplant Infectious Disease*, 24(6), p.e13916.

Wyld, M., Morton, R.L., Hayen, A., Howard, K. and Webster, A.C., 2012. "A systematic review and meta-analysis of utility-based quality of life in chronic kidney disease treatments." *PLoS Medicine*. 2012;9(9):e1001307.

Zarinsefat, A., Gulati, A., Shui, A., Braun, H., Rogers, R., Hirose, R., Ascher, N. and Stock, P., 2022. Long-term outcomes following kidney and liver transplant in recipients with HIV. *JAMA Surgery*, 157(3), pp.240-247.