DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Docket No. HRSA-2024-0001

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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

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Department of Health and Human Services

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I. **Introduction and Summary**

A. Introduction

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

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities. This analysis indicates that this proposed rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

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

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

B. Overview of Benefits, Costs, and Transfers

This proposed rule would, if finalized, remove the current research and institutional review board (IRB) requirements for transplants of human immunodeficiency virus (HIV)-positive kidneys and livers. This would result in impacts related to changes in the number of kidney and liver

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

transplants performed annually. We monetize benefits associated with increases in life expectancy for organ transplant recipients and, for kidney transplant recipients, benefits associated with improved quality of life and time savings from fewer kidney dialysis visits. We monetize costs from medical expenditures associated with organ transplantation; for kidney transplants, we report impacts that are net of medical expenditures associated with kidney dialysis. We also monetize costs associated with organ transplant centers reading and understanding the rule, reviewing policies and procedures, and training staff. We report the shift in expenditures associated with kidney dialysis to expenditures associated with kidney transplantation separately as transfers. We estimate that the annualized benefits over a 10-year time horizon covering 2025 through 2034 would range from $561 million to $1.26 billion at a 2 percent discount rate, with a primary estimate of $900 million. The annualized costs would range from $134 million to $174 million, with a primary estimate of $154 million. The annualized transfers would range from $24 million to $39 million, with a primary estimate of $31 million.

Table 1. Summary of Impacts of the Proposed Rule (millions of constant 2023 dollars)

Category	Primary Estimate	Low Estimate	High Estimate	Dollar Year or Unit	Discount Rate	Time Horizon	Notes
BENEFITS							
Annualized monetized benefits	$900	$561	$1,261	2023	2%	2025-2034	Increased life expectancy for organ transplant recipients; improved quality of life for kidney transplant recipients; time savings from fewer kidney dialysis visits
Annualized quantified, but non-monetized, benefits	147	129	166	People affected	2%	2025-2034	Improved quality of life for liver transplant recipients
Unquantified benefits						2025-2034	Time savings for caregivers; cost savings related to removing the research and institutional review board requirements
COSTS							
Annualized monetized costs	$154	$134	$174	2023	2%	2025-2034	Net costs associated with organ transplants; costs associated with organ transplant centers reading and understanding the rule, reviewing policies and procedures, and training staff
TRANSFERS							

Annualized monetized transfers	$31	$24	$39	2023	2%	2025-2034	Shift in expenditures associated with kidney dialysis to expenditures associated with kidney transplantation
NET BENEFITS							
Annualized monetized net benefits	$746	$412	$1,101	2023	2%	2025-2034	

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

We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

II. Preliminary 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 (IRB) under specified research criteria. HRSA published a final rule to implement the HOPE Act on May 8, 2015.[2] Under these 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. This proposed rule, if finalized, would remove the current research and IRB requirements for transplants of donor kidneys and livers with HIV.

B. Analytic Approach

In conducting this analysis, we began by identifying the most consequential impacts that would likely occur under the proposed rule, if finalized. For this proposed 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 organ 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 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 spending on kidney dialysis. We report the net impact on medical spending as the costs of the proposed rule, and separately report the cost savings as distributional impacts, as they represent a transfer of monetary payments that would go to entities providing medical care associated with kidney dialysis to entities providing medical care associated with kidney transplantation. We quantify

[2] 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.

the time spent by organ transplant centers to read and understand the proposed 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 but not monetized impacts, and discuss other non-quantified impacts.

For the purposes of this analysis, we assume that the proposed rule, if it is finalized, will begin to take effect in 2025. We model several important sources of uncertainty with our quantified impact estimates, including several factors that affect the number of kidneys and livers that would be transplanted under the proposed rule, and also uncertainty about when the effects of the proposed rule would 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 proposed rule, we also 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.

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. To simplify the narrative, we report several intermediate calculations using our primary estimates, while our full range of estimates is presented in a Monte Carlo simulation. All monetary estimates are reported in constant 2023 dollars unless otherwise noted.

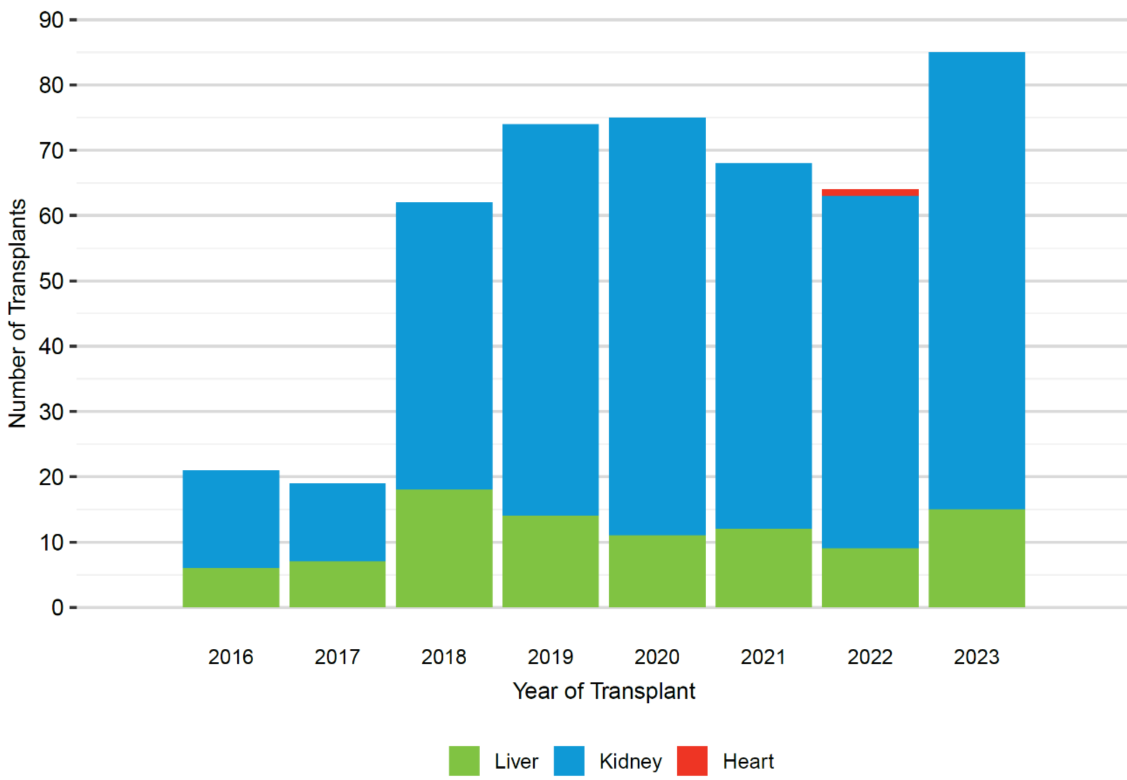
C. Baseline Conditions

The Organ Procurement and Transplantation Network (OPTN) membership directory lists 247 transplant centers with active member status.[3] Among these, 141 centers have both kidney and liver transplant programs; 90 centers have a kidney program but not a liver program; 1 center has a liver program but not a kidney program; and 15 centers have at least one organ program but no programs for kidneys or livers. As of January 12, 2024, there are 53 kidney and liver programs among 29 centers with HOPE Act IRB approval.

Between January 1, 2016 and December 31, 2023, 468 organs have been transplanted between donors with HIV and patients,[4] all occurring under the requirements of the 2015 HOPE Act final rule and additional research criteria published separately.[5] Figure 1 presents the annual counts of kidney, liver, and heart transplant recipients for calendar years 2016 through 2023. To project baseline transplants over the time horizon of the analysis, we adopt the annual average of kidney and liver transplant recipients over the last five full years of data, covering 2019 through 2023. Over this period, we observe 304 kidney transplants (including 3 living donors) and 61 liver transplants, for an average of 60.8 kidney transplants and 12.2 liver transplants per year.

[3] Organ Procurement and Transplantation Network. "Search Membership." https://optn.transplant.hrsa.gov/about/search-membership/. Accessed August 25, 2024.
[4] Data from the Organ Procurement and Transplantation Network, Health Resources and Services Administration, U.S. Department of Health and Human Services.
[5] 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.

Figure 1. HIV Positive Kidney, Liver, and Heart Transplant Recipients between January 01, 2016 and December 31, 2023



D. Impacts on Kidney and Liver Transplants

Our analysis of the outcomes anticipated under the proposed rule begins with estimates of the donor organs with HIV available for transplant. For the proposed rule scenario, we initially adopt estimates of 192 kidneys and 247 livers from a study that retrospectively reviewed medical charts for deceased patients who had HIV, estimated probabilities of recovering organs from these patients using donor yield models, and then extrapolated the results from the one metropolitan area directly included (Philadelphia, for which the estimate was four to five new deceased donors annually) to match the U.S. population.[6]

Below, we discuss several adjustments to these estimates. We account for a range of uncertainty in these projections by adopting a range of adjustments for several key parameters. 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 used to estimate the range of total benefit and cost estimates reported in Table 1 and the summary.

[6] 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.

Deceased Organ Donation Consent Rate

The kidney and liver estimates 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 likely introduce upward bias into our estimated impacts on kidney and liver transplants. One study notes that "overall 75% of potential donors are estimated to consent annually,"[7] drawing from self-reported consent rate data from organ procurement organizations. Another study reports a lower share, 68.9%, calculated using potential donor-level data.[8] When modeling this parameter, we adopt a uniform distribution with range [0.689,0.750], and adopt the mean of the distribution, about 0.72, as our primary estimate. As an example of how this multiplier and other multipliers are incorporated into this analysis, applying the primary estimate of the organ donation consent rate of 0.72 reduces the initial estimate from 192 to 138 kidneys per year.

Size of the Deceased Donor Pool

We considered adjustments related to the size of the deceased donor pool. During the study period, the authors reported an average of 16,434 annual deaths among individuals with HIV. In 2022, the comparable number was 19,310,[9] suggesting that the donor pool in 2022 would have been approximately 18% larger than in the study period;[10] however, this number includes mortality from all causes and corresponds to a year with significant numbers of excess deaths associated with COVID-19. Data from 2019 indicate 15,815 deaths among individuals with HIV,[11] which would indicate a donor pool in 2019 that was about 4% lower than the study period. In our simulations, we adopt a range of multipliers to capture the potential change in the size of the donor pool. For our lower-bound estimate, we adopt a multiplier of 0.96, corresponding to the 2019 data. For our upper-bound estimate, we adopt a multiplier of 1.18, corresponding to the 2022 data. We identify a central estimate of the multiplier of 1, which is consistent with no change in the size of the donor pool from the underlying study. When modeling the distribution of possible values for this multiplier, we adopt a triangle distribution with range [0.96, 1.18] and mode 1, and a primary estimate of 1.05, corresponding to the mean of the triangle distribution.

We also considered other sources to quantify the potential donor organ pool, including one study that identified approximately 500–600 annual deceased donors who had HIV,[12] and estimated that they represent 63 kidney-only donors, 221 liver-only donors, and 250 kidney and liver donors. We did not incorporate the findings of this study into our primary analysis, but present a

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[7] Siminoff, L. A., Agyemang, A. A., & Traino, H. M. (2013). Consent to organ donation: a review. Progress in transplantation (Aliso Viejo, Calif.), 23(1), 99–104. https://doi.org/10.7182/pit2013801.

[8] 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.

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

[10] $(19{,}310 - 16{,}434) / 16{,}434 \approx 0.175$.

[11] Internet Archive. Wayback Machine. January 1, 2022 capture for https://web.archive.org/web/20220101093511/https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/. Accessed August 25, 2024.

[12] 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.

separate sensitivity analysis in Section II.H that reports impact estimates that are consistent with this study. We request comment on whether these additional estimates should be included in the range of potential policy impacts. More broadly, we invite comments on any studies that could assist in refining the quantitative projections in subsequent analyses.

Living Donors

We considered adjustments related to the number of potential living donors. The estimates reported above come from a study of deceased donors who had HIV. 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%.[13] If the ratio of transplants from living donors to deceased donors extends to the change in organs anticipated under the proposed rule, this would increase the total transplants by about 32% 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,[14] with 1 kidney per living donor, and 1 liver transplant per living or decreased live donor. To account for uncertainty in the additional transplanted organs from living donors, we adopt multipliers specific to each organ. 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 organs anticipated under the proposed rule. For kidneys, we identify a central estimate of about 1.01, corresponding to the additional kidney transplants from living donors occurring under the research and IRB requirements of the 2015 HOPE Act final rule.[15] Under these requirements, no liver transplants from living donors with HIV have occurred as of December 31, 2023, 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 the potential changing size of the living donor pool over time from our adjusted 2022 estimate through 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 the number of new HIV infections, which is generally decreasing.[16] Ultimately, this analysis does not make further adjustments to account for the potential change in the size of the live donor pool since 2022.

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[13] 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.
[14] 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.
[15] Among 304 kidney transplants, 3 were from living donors. 304 /301 ≈ 1.01.
[16] HIV.gov. August 15, 2024. "U.S. Statistics." https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/.

False-Positive Donors

In addition to increasing the number of kidneys and livers transplanted from donors with HIV, the proposed 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."[17] The authors note that organs from this pool of potential donors were generally discarded 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 proposed 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 quantified this potential impact.

Timing of Impacts on Kidney and Liver Transplants

Combining the initial estimates with the full range of multipliers, we compute a range of 127 to 224 kidneys transplanted annually, with a primary estimate of 161; and a range of livers transplanted annually from 164 to 230, with a primary estimate of 189.

The above estimates correspond to the number of kidneys and livers transplanted when the impacts of the proposed rule fully materialize. This is unlikely to occur in the first year following publication of a subsequent final rule if the proposed rule is finalized. We adopt an implementation timeline that is informed by the experience of the HOPE Act and 2015 final rule. For our primary estimate, we adopt 4 years, which corresponds to the number of years between publication of the final rule in 2015 and 2019, when the total number of transplanted organs (74) first met or exceeded our baseline estimates. We assume that the impacts are phased in linearly, such that 25% of the impacts occur in the first year, 50% occur in the second year, 75% occur in the third year, and 100% of the impacts occur in the fourth year and subsequent years. 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], and the mean of the distribution, ¼, as our primary estimate. Figures 2A and 2B below depict the number of kidney and liver transplants for each year under the baseline scenario, and for a range of outcomes under the proposed rule. For these figures, the range of the shaded area corresponds to a 90% confidence interval from the simulation in Section II.H.

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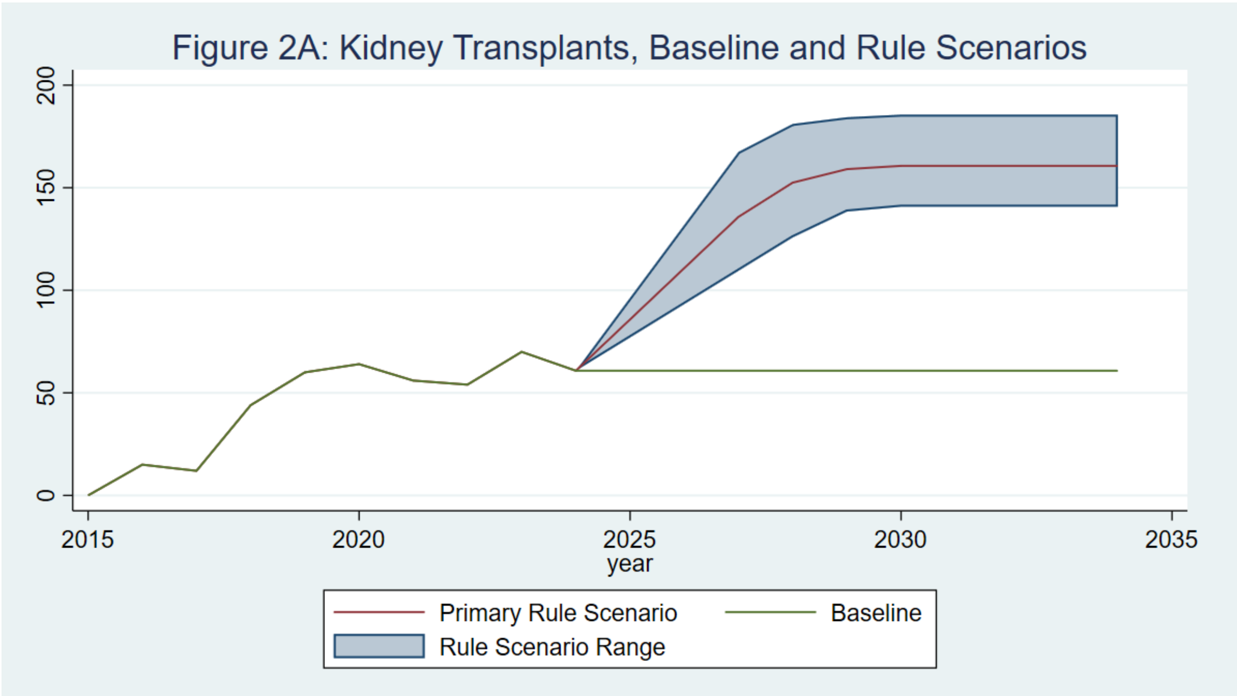
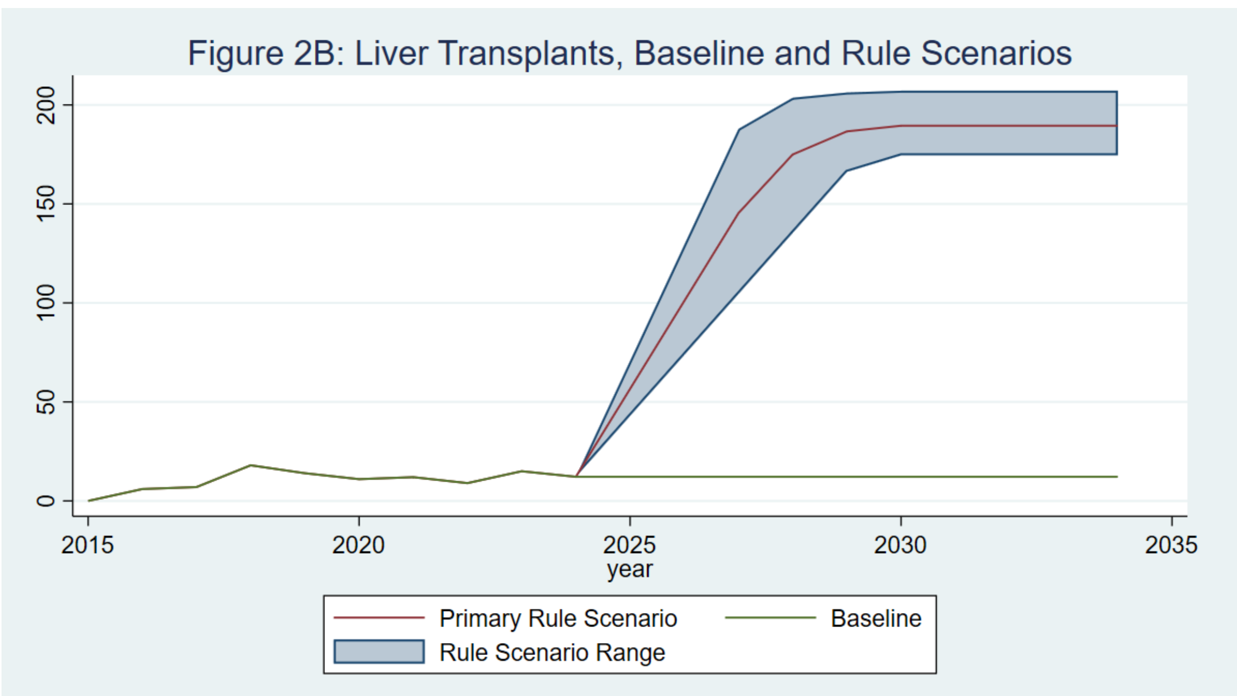
[17] Durand, C. M., Halpern, S. E., Bowring, M. G., Bismut, G. A., Kusemiju, O. T., Doby, B., Fernandez, R. E., Kirby, C. S., Ostrander, D., Stock, P. G., Mehta, S., Turgeon, N. A., Wojciechowski, D., Huprikar, S., Florman, S., Ottmann, S., Desai, N. M., Cameron, A., Massie, A. B., Tobian, A. A. R., 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.



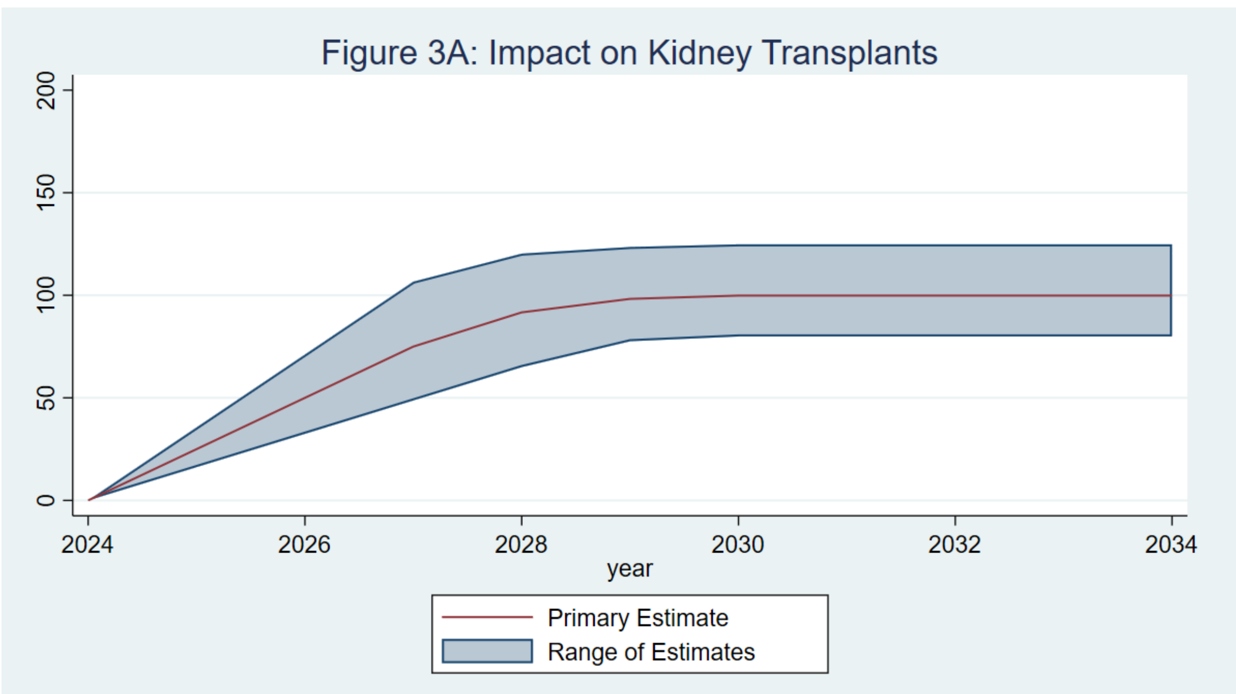


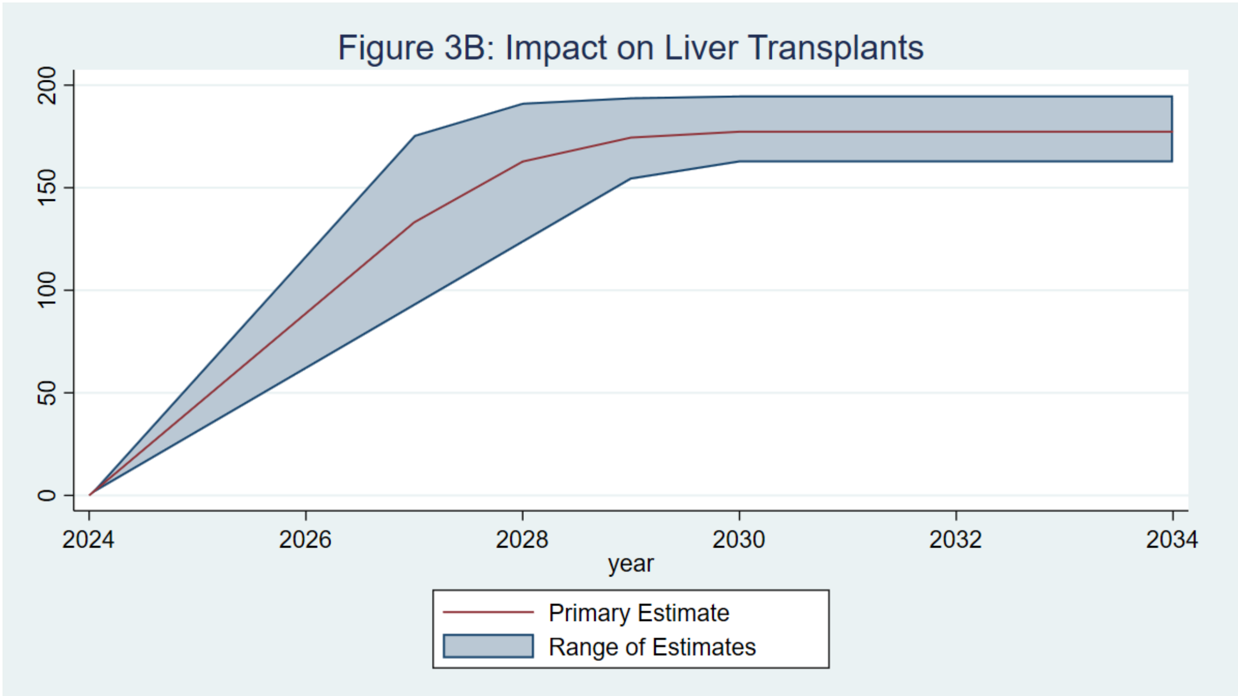
To calculate the impact of the proposed rule on transplants, we subtract our baseline estimates of the organ transplants that would occur annually without the proposed rule. Table 2 reports the number of kidneys and livers transplanted under the baseline, under the proposed rule, and the impacts attributable to the proposed rule. Figure 3 presents the impacts on kidney and liver transplants. For these figures, the range of the shaded area corresponds to a 90% confidence interval from the simulation in Section II.H.

Table 2. Impacts on Kidney and Liver Transplants, Primary Estimates

Year	Baseline Scenario		Policy Scenario		Impact	
	Kidney	Liver	Kidney	Liver	Kidney	Liver
2025	61	12	86	57	25	44
2026	61	12	111	101	50	89
2027	61	12	136	145	75	133
2028	61	12	161	189	100	177
2029	61	12	161	189	100	177
2030	61	12	161	189	100	177
2031	61	12	161	189	100	177
2032	61	12	161	189	100	177
2033	61	12	161	189	100	177
2034	61	12	161	189	100	177

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





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.[18] When the effects of the proposed rule fully materialize, the additional 100 kidney and 177 liver transplants would 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 1.7%.

E. Benefits of the Proposed Rule

On average, organ transplants significantly extend lives. There is extensive literature on life expectancy before and after transplant, quality of life, and cost savings for transplant patients. For example, a review of the cost effectiveness of the HOPE Act found essentially universal agreement that kidney transplants were not only substantially life-extending, but also cost-reducing.[19] The authors performed an extensive literature search and found that from 1968 to 2007, seventeen studies assessed the cost-effectiveness of renal transplantation. 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

[18] Health Resources and Services Administration. Organ Donation and Transplantation. https://data.hrsa.gov/topics/health-systems/organ-donation.
[19] Huang, E., et al., "The Cost-Effectiveness of Renal Transplantation," When Altruism Isn't Enough, edited by Sally Satel (AEI Press, 2008).

compared to those remaining on dialysis.[20] Accordingly, the per-patient potential benefits of the proposed rule would be substantial.

This section describes our approach to quantifying the health benefits associated with kidney and liver transplants and time-saving benefits associated with fewer kidney dialysis treatments. These benefits would be realized by recipients living with HIV receiving organs with HIV as a direct result of the proposed 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.[21] Benefits would, in some cases, instead be experienced by recipients (with or without HIV) receiving organs from donors without HIV through reduced waiting times.[22]

We note that the estimates in this section represent averages across patients who vary widely in age, medical condition, and life expectancy, as well as type of organ failure. For example, the sickest patients typically have very low life expectancies without transplant so they stand to gain the most years of life from a transplant. However, these same patients, on average, have slightly lower survival rates post-transplant. Organ and patient survival issues are complex and dealt with by detailed policies and procedures developed and used by the transplant community. These policies are reviewed and revised frequently based on experience and changing technology—over time, the success rate from using marginal organs and in transplanting older and sicker patients have both increased substantially. There are additional complexities that we have not used in these broad 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.

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."[23] 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:

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

[20] 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.
[21] 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.
[22] See Section D of the notice of proposed rulemaking for a discussion.
[23] 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.

Adopting parameters m = 10, n = 19, and r = 1/(1+2%), this expression evaluates to 7.5 life years, which we adopt as the average discounted change in life expectancy per kidney transplant recipient.

Impacts of Liver Transplants on Mortality

One potentially complicating factor when attempting to estimate the impacts of liver transplants on mortality is that survival outcomes depend heavily on the severity of the condition of the transplant candidate. HRSA's Organ Procurement and Transplantation Network 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."[24]

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."[25] Another study found that patients with a MELD score of 40 "have a 3-month survival probability of almost 0% without [liver transplantation]."[26] We note, however, that both studies applied scores that predate a July 13, 2023 update[27] to the data used in the MELD calculation formula.

To quantify the change in life expectancy for liver transplant recipients attributable to the proposed rule, we adopt estimates from a study that estimated survival benefits of liver transplants that vary by MELD score.[28] 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, 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 = 6.30, and r = 1/(1+2%). This expression evaluates to 6.6 life years,

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[24] Organ Procurement and Transplantation Network, Health Resources and Services Administration. 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.
[25] 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.
[26] 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.
[27] Organ Procurement and Transplantation Network, Health Resources and Services Administration. "MELD Calculator." https://optn.transplant.hrsa.gov/data/allocation-calculators/meld-calculator/.
[28] 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.

which we adopt as the average discounted change in life expectancy per liver transplant recipient.

Impacts of Transplants on Morbidity

We anticipate that the proposed rule would also result in improvements in the health-related quality of life for individuals receiving organ transplants.[29][30] 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.[31] 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.[32] 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 this proposed rule.

Valuing Mortality and Morbidity Risk Reductions

The HHS *Guidelines for Regulatory Impact Analysis*[33] discuss an approach to valuing mortality risk reductions based on estimates of individual willingness to pay, commonly referred to as the value per statistical life. 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.[34] The *Guidelines* and an appendix published subsequently[35] 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

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[29] 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.

[30] 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.

[31] 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.

[32] 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.

[33] 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.

[34] 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.

[35] 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.

(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,[36] 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).[37] HHS computes VQALY similar to VSLY, except this metric incorporates measurements of age-varying, but otherwise population-average, health-related quality-of-life scores.[38] 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%[39] and an assumption that the VSL income elasticity is 1.0. Unrounded estimates of HHS's standard values used in this analysis are available online.[40]

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 $3.2 million, equal to the 6.6 statistical life years calculated above times the same VSLY. Table 3,

[36] 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.

[37] 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.

[38] 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.

[39] 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.

[40] 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.

below, reports primary estimates of the annual impacts on kidney transplants, and associated health benefits, and Table 4 reports comparable estimates for livers.

Time Savings Associated with 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."[41] We also assume that dialysis patients spend, on average, an additional half hour for a round-trip traveling to each treatment.[42] Over the course of a year, this is about 704.4 hours per year for each patient on dialysis.[43] 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 monetize these impacts, we apply an estimate of an hourly value of time of $19.24,[44] following HHS's default approach to monetizing changes in time use for unpaid activities.[45] This default estimate might underestimate the benefits experienced by individuals, since it does not account for the discomfort some individuals experience during treatment;[46] 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.[47] Table 3 reports primary estimates of the time-saving benefits associated with kidney transplants.

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

[42] 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/.

[43] (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.

[44] 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.

[45] 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.

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

[47] 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 result in a time-saving benefit per individual of about $243,000, which would increase the present value and annualized total benefits of kidney transplants reported in Table 3 by about 3%.

Table 3. Benefits from Kidney Transplants, Primary Estimates (millions of 2023 dollars)

Year	Impact on Transplants	Health Benefit per Transplant	Time-Saving Benefit per Transplant	Health Benefits	Time-Saving Benefits	Total Benefits
2025	25	$4.3	$0.1	$109	$3	$112
2026	50	$4.4	$0.1	$219	$6	$225
2027	75	$4.4	$0.1	$332	$9	$341
2028	100	$4.5	$0.1	$447	$12	$460
2029	100	$4.5	$0.1	$452	$12	$464
2030	100	$4.6	$0.1	$457	$12	$469
2031	100	$4.6	$0.1	$461	$12	$473
2032	100	$4.7	$0.1	$466	$12	$478
2033	100	$4.7	$0.1	$470	$12	$483
2034	100	$4.8	$0.1	$475	$12	$487
Present Value (2%)	752			$3,441	$92	$3,532
Annualized (2%)	84			$383	$10	$393

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

Table 4. Benefits from Liver Transplants, Primary Estimates (millions of 2023 dollars)

Year	Impact on Transplants	Health Benefit per Transplant	Health Benefits
2025	44	$3.8	$169
2026	89	$3.9	$341
2027	133	$3.9	$517
2028	177	$3.9	$697
2029	177	$4.0	$704
2030	177	$4.0	$711
2031	177	$4.0	$718
2032	177	$4.1	$725
2033	177	$4.1	$732
2034	177	$4.2	$740
Present Value (2%)	1,335		$5,356
Annualized (2%)	149		$596

Note: Health benefits are mortality risk reductions.

Discussion of Additional Sources of Benefits

We identify several additional sources of benefits not otherwise captured in the monetized benefits reported above. First, we anticipate some quality-of-life improvements for liver 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,[48] we might anticipate additional benefits associated with reductions in patient-borne utility costs.[49]

F. Costs and Cost Savings of the Proposed Rule

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.[50] The 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 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.[51] 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 spending on immunosuppressant drugs matches the difference between actual first-year costs and the charge estimates. Thus, we provisionally adopt the $1,034,153 per liver 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 $371,745 over 10 years, while patients receiving "deceased donor organs deemed to be at increased risk of viral disease transmission by the US Public

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[48] 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.

[49] 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/.

[50] 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 using annual figures of CPI-U. U.S. Bureau of Labor Statistics. CPI for all Urban Consumers (CPI-U), Not Seasonally Adjusted, https://data.bls.gov/timeseries/CUUR0000SA0.

[51] 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.

Health Service" (PHS) incur expenses of $390,752 over 10 years.[52] From these estimates, we derive a $19,006 net impact on medical spending, which we adopt as our primary estimate of the cost per kidney transplant. In supplementary digital content, this study reports comparable cost estimates covering a longer time horizon. Over 20 years, they find that patients on dialysis incur expenses of $539,198, while patients receiving donor organs incur expenses of $609,367.[53] Thus, switching from dialysis would result in a net impact on medical spending of $70,169 per kidney transplant. We consider these alternative estimates in a sensitivity analysis of the costs and transfers associated with kidney transplants.

We report the net impact on medical spending as the costs of the proposed rule, and separately report the partially offsetting cost-saving impacts as distributional impacts, which represent a net transfer in monetary payments that would go to entities providing medical care associated with kidney dialysis to entities providing medical care associated with kidney transplantation. Table 5A 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 5A presents a sensitivity analysis that applies the alternative estimates for costs and transfers covering a 20-year time period. Table 6 reports primary estimates of the impacts on liver transplants and the costs associated with those transplants.

[52] 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 using annual figures of CPI-U. U.S. Bureau of Labor Statistics. CPI for all Urban Consumers (CPI-U), Not Seasonally Adjusted, https://data.bls.gov/timeseries/CUUR0000SA0.

[53] 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 using annual figures of CPI-U. U.S. Bureau of Labor Statistics. CPI for all Urban Consumers (CPI-U), Not Seasonally Adjusted, https://data.bls.gov/timeseries/CUUR0000SA0.

Table 5A. Costs and Transfers Associated with Kidney Transplants, Primary Estimates (millions of 2023 dollars)

Year	Impact on Transplants	Costs per Transplant	Transfers per Transplant	Costs	Transfers
2025	25	$0.02	$0.37	$0.5	$9.3
2026	50	$0.02	$0.37	$0.9	$18.6
2027	75	$0.02	$0.37	$1.4	$27.8
2028	100	$0.02	$0.37	$1.9	$37.1
2029	100	$0.02	$0.37	$1.9	$37.1
2030	100	$0.02	$0.37	$1.9	$37.1
2031	100	$0.02	$0.37	$1.9	$37.1
2032	100	$0.02	$0.37	$1.9	$37.1
2033	100	$0.02	$0.37	$1.9	$37.1
2034	100	$0.02	$0.37	$1.9	$37.1
Present Value (2%)	752			$14.3	$279.6
Annualized (2%)	84			$1.6	$31.1

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

Table 5B. Costs and Transfers Associated with Kidney Transplants, Alternative Estimates (millions of 2023 dollars)

Year	Impact on Transplants	Costs per Transplant	Transfers per Transplant	Costs	Transfers
2025	25	-$0.07	$0.61	-$1.8	$15.2
2026	50	-$0.07	$0.61	-$3.5	$30.4
2027	75	-$0.07	$0.61	-$5.3	$45.7
2028	100	-$0.07	$0.61	-$7.0	$60.9
2029	100	-$0.07	$0.61	-$7.0	$60.9
2030	100	-$0.07	$0.61	-$7.0	$60.9
2031	100	-$0.07	$0.61	-$7.0	$60.9
2032	100	-$0.07	$0.61	-$7.0	$60.9
2033	100	-$0.07	$0.61	-$7.0	$60.9
2034	100	-$0.07	$0.61	-$7.0	$60.9
Present Value (2%)	752			-$52.8	$458.4
Annualized (2%)	84			-$5.9	$51.0

Note: costs are measured as the net impact on medical spending; transfers are the shifts in expenditures associated with kidney dialysis to expenditures associated with kidney transplantation; negative costs indicate these impacts are associated with reductions in total medical expenditures.

Table 6. Costs Associated with Liver Transplants, Primary Estimates (millions of 2023 dollars)

Year	Impact on Transplants	Costs per Transplant	Costs
2025	44	$1.03	$45.8
2026	89	$1.03	$91.7
2027	133	$1.03	$137.5
2028	177	$1.03	$183.3
2029	177	$1.03	$183.3
2030	177	$1.03	$183.3
2031	177	$1.03	$183.3
2032	177	$1.03	$183.3
2033	177	$1.03	$183.3
2034	177	$1.03	$183.3
Present Value (2%)	1,335		$1,380.5
Annualized (2%)	149		$153.7

Costs Associated with Reading and Understanding the Rule

We anticipate that most transplant centers with at least one active organ transplant program would incur costs associated with becoming familiar with the proposed rule. To quantify this impact, we estimate the time spent to read and understand the rule. We estimate that it would take an individual about 45 minutes to read the notice of proposed rulemaking (NPRM).[54] We assume that, on average, one individual at each transplant center would read the NPRM. Thus, across 247 transplant centers, this would amount to about 185 hours.[55]

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)."

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.[56] 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

[54] This estimate is consistent with an individual reading the notice of proposed rulemaking, which contains about 10,000 words, at approximately 200 to 250 words per minute.
[55] 247 * 45 minutes = 11,115 minutes = 185.25 hours.
[56] 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.

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 $19,714.

Costs Associated with Reviewing Policies and Procedures, and Training Staff

The proposed rule would likely result in some additional organ transplant centers choosing to transplant donor kidneys and livers with HIV. To produce an upper-bound estimate, we begin with 247 total transplant centers with active programs, subtract 15 centers that do not have a kidney or liver program, and further subtract 29 centers that have HOPE Act IRB approval under the baseline scenario. This leaves 203 transplant centers as our upper-bound estimate. For the purposes of this analysis, we adopt a primary estimate of 101.5 transplant centers by assuming that half would choose to transplant donor kidneys and livers with HIV.

We anticipate that each of these transplant centers would incur costs associated with reviewing their policies and procedures and training staff prior to transplanting donor kidneys and livers with HIV. To quantify these impacts, we assume that an individual at each transplant center would spend about 16 hours on average to review and, if necessary, update their policies, procedures, and training materials. Across 101.5 transplant centers, this is 1,624 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 1,624 total hours across all transplant centers and estimate a one-time cost of $172,826. We further assume that staff at each center would spend an average of 40 hours on training, inclusive of total time spent by staff delivering and receiving training. Across 101.5 transplant centers, this is 4,060 total hours. For this impact, we identify a pre-tax hourly wage for health practitioners and technical occupations of $38.86 per hour.[57] 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 $77.72. We multiply this fully loaded wage rate by 4,060 total hours across all transplant centers and estimate a one-time cost of $315,543.

Summary of Monetized Costs and Discussion of Additional Sources of Costs and Cost Savings

Table 7 summarizes our primary estimates of the costs associated with the proposed rule. We model the one-time costs associated with reading and understanding the 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 proposed rule, if finalized, would potentially forgo some information gained from 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 would likely accrue to the 53 kidney and liver programs among 29 centers with HOPE Act IRB approval.

[57] 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.

Table 7. Costs of the Proposed Rule, Primary Estimates (millions of 2023 dollars)

Year	Kidney Transplants	Liver Transplants	Reading and Understanding	Policies and Procedures	Training	Total
2025	$0.47	$45.83	$0.02	$0.17	$0.32	$46.81
2026	$0.95	$91.65	$0.00	$0.00	$0.00	$92.60
2027	$1.42	$137.48	$0.00	$0.00	$0.00	$138.90
2028	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
2029	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
2030	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
2031	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
2032	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
2033	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
2034	$1.90	$183.31	$0.00	$0.00	$0.00	$185.20
Present Value (2%)	$14.30	$1,380.50	$0.02	$0.17	$0.31	$1,395.29
Annualized (2%)	$1.59	$153.69	$0.00	$0.02	$0.03	$155.33

G. Analysis of Regulatory Alternatives to the Proposed Rule

We considered several alternatives to the proposed rule, and this analysis assesses the benefits and costs of several of these alternatives against a common baseline scenario. We discuss several additional alternatives in the Preamble. This section briefly describes the general policy approach of the alternatives, and Table 8 presents the present value of benefits, costs, transfers, and net benefits for each of these alternatives. This analysis is limited to an assessment of economic efficiency and distributional consequences of the policy alternatives, and does not speak to the legal viability of any alternative.[58]

Alternative 1, "Faster": Remove the research and IRB requirements faster

For the purposes of this regulatory impact analysis, we considered a policy alternative of implementing this 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.[59] To assess the benefits and costs of this alternative, we assume that the impacts would begin 6 months earlier than the estimates of the proposed rule. We operationalize this

[58] "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.

[59] "Agencies must also consider a range of regulatory and non-regulatory alternatives, regardless of whether the statute or other authorities prescribe the option they can ultimately implement." 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. Page 6.

difference through discounting, multiplying the present value of the proposed rule's impacts by about 1.01.[60]

Alternative 2, "Kidneys Only": Remove the research and IRB requirements for kidneys

We assess the policy alternative of lifting the research and IRB requirements for only kidneys, leaving the requirements in place for livers.

Alternative 3, "Livers Only": Remove the research and IRB requirements for livers

We assess the policy alternative of lifting the research and IRB requirements for only livers, leaving the requirements in place for kidneys.

Table 8. Comparison of Policy Alternatives (present value, millions of 2023 dollars)

Impact	Proposed Rule	Faster	Kidneys Only	Livers Only
Benefits	$8,888	$8,977	$3,532	$5,356
Costs	$1,395	$1,409	$15	$1,381
Transfers	$280	$282	$280	$0
Net Benefits	$7,493	$7,567	$3,518	$3,975

In addition to impacts that we monetize in Table 8, we note that Alternative 1, "Sooner," compared to the proposed rule, could entail potential forgone benefits associated with information gained through the public comment process.

H. Uncertainty and Sensitivity Analysis

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.[61] Table 9 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 five parameters in Section II.D, and discuss the source for the last two parameters in Section II.E.

For each trial of the simulation, we sample one random value for each of the seven parameters. Next, we repeat the full analysis described in sections II.D, II.E, and 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.

[60] $(1/(1+2\%))^{\wedge}(-1/2) \approx 1.01$.
[61] 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 9. Distributions for Parameters Modeled with Uncertainty

Parameter	Distribution	Min	Max	Mode	Standard Deviation	Mean
Deceased Organ Donation Consent Rate	Uniform	0.69	0.75	N/A	0.02	0.72
Size of the Deceased Donor Pool	Triangle	0.96	1.88	1.00	0.05	1.05
Living Donors, Kidney	Triangle	1.00	1.33	1.01	0.08	1.11
Living Donors, 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 10 reports the impacts associated with kidney transplants, including the health benefits, time benefits, and costs for each year of the analysis. Table 11 reports the yearly impacts associated with liver transplants. Table 12 reports the yearly benefits, costs, transfers, and net benefits, and Table 13 reports the present value and annualized impacts for the 10-year time horizon of the analysis.

Table 10. Yearly Impacts Associated with Kidney Transplants

year: 2025	Mean	p5	p95
Impact on Transplants, Kidneys	24.999	16.248	35.551
Health Benefits, Kidneys	108.702	58.242	173.498
Time Benefits, Kidneys	3.104	2.018	4.414
Costs, Kidneys	.474	.308	0.674
2026			
Impact on Transplants, Kidneys	49.997	32.496	71.101
Health Benefits, Kidneys	219.578	117.648	350.465
Time Benefits, Kidneys	6.208	4.035	8.829
Costs, Kidneys	.948	.616	1.348
2027			
Impact on Transplants, Kidneys	74.996	48.743	106.652
Health Benefits, Kidneys	332.66	178.237	530.955
Time Benefits, Kidneys	9.313	6.053	13.243
Costs, Kidneys	1.422	.924	2.022
2028			
Impact on Transplants, Kidneys	91.672	64.991	120.308
Health Benefits, Kidneys	410.778	234.802	618.965
Time Benefits, Kidneys	11.383	8.07	14.939
Costs, Kidneys	1.738	1.232	2.281
2029			
Impact on Transplants, Kidneys	98.256	77.591	123.571
Health Benefits, Kidneys	444.642	265.234	651.519
Time Benefits, Kidneys	12.201	9.635	15.344
Costs, Kidneys	1.863	1.471	2.343
2030			
Impact on Transplants, Kidneys	99.872	79.938	124.851
Health Benefits, Kidneys	456.457	273.908	665.655
Time Benefits, Kidneys	12.402	9.926	15.503
Costs, Kidneys	1.894	1.516	2.367
2031			
Impact on Transplants, Kidneys	99.872	79.938	124.851
Health Benefits, Kidneys	461.022	276.647	672.312
Time Benefits, Kidneys	12.402	9.926	15.503
Costs, Kidneys	1.894	1.516	2.367
2032			
Impact on Transplants, Kidneys	99.872	79.938	124.851
Health Benefits, Kidneys	465.632	279.414	679.035
Time Benefits, Kidneys	12.402	9.926	15.503
Costs, Kidneys	1.894	1.516	2.367
2033			
Impact on Transplants, Kidneys	99.872	79.938	124.851
Health Benefits, Kidneys	470.288	282.208	685.825
Time Benefits, Kidneys	12.402	9.926	15.503
Costs, Kidneys	1.894	1.516	2.367
2034			
Impact on Transplants, Kidneys	99.872	79.938	124.851
Health Benefits, Kidneys	474.991	285.03	692.683
Time Benefits, Kidneys	12.402	9.926	15.503
Costs, Kidneys	1.894	1.516	2.367

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 11. Yearly Impacts Associated with Liver Transplants

year: 2025	Mean	p5	p95
Impact on Liver Transplants	44.38	30.805	58.568
Health Benefits, Livers	146.738	82.47	224.624
Costs, Livers	45.896	31.857	60.568
2026			
Impact on Liver Transplants	88.76	61.611	117.136
Health Benefits, Livers	296.41	166.59	453.741
Costs, Livers	91.792	63.715	121.136
2027			
Impact on Liver Transplants	133.14	92.416	175.704
Health Benefits, Livers	449.061	252.384	687.417
Costs, Livers	137.687	95.572	181.705
2028			
Impact on Liver Transplants	162.757	123.221	191.447
Health Benefits, Livers	554.543	332.23	798.127
Costs, Livers	168.316	127.429	197.986
2029			
Impact on Liver Transplants	174.444	153.99	194.096
Health Benefits, Livers	600.249	376.274	830.102
Costs, Livers	180.402	159.25	200.725
2030			
Impact on Liver Transplants	177.311	162.34	195.013
Health Benefits, Livers	616.197	388.212	847.559
Costs, Livers	183.366	167.884	201.673
2031			
Impact on Liver Transplants	177.311	162.34	195.013
Health Benefits, Livers	622.359	392.094	856.034
Costs, Livers	183.366	167.884	201.673
2032			
Impact on Liver Transplants	177.311	162.34	195.013
Health Benefits, Livers	628.582	396.015	864.595
Costs, Livers	183.366	167.884	201.673
2033			
Impact on Liver Transplants	177.311	162.34	195.013
Health Benefits, Livers	634.868	399.975	873.241
Costs, Livers	183.366	167.884	201.673
2034			
Impact on Liver Transplants	177.311	162.34	195.013
Health Benefits, Livers	641.217	403.975	881.973
Costs, Livers	183.366	167.884	201.673

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 12. Yearly Monetized Impacts

year: 2025	Mean	p5	p95
Benefits	258.544	144.39	397.989
Costs	46.878	32.678	61.706
Transfers	9.271	6.026	13.184
Net Benefits	211.666	105.719	341.253
2026			
Benefits	522.196	291.622	803.861
Costs	92.74	64.34	122.395
Transfers	18.542	12.051	26.368
Net Benefits	429.456	215.335	691.331
2027			
Benefits	791.034	441.738	1217.735
Costs	139.109	96.51	183.593
Transfers	27.813	18.077	39.553
Net Benefits	651.924	327.385	1048.869
2028			
Benefits	976.704	583.04	1415.071
Costs	170.054	128.679	200.041
Transfers	33.998	24.103	44.617
Net Benefits	806.65	428.756	1226.479
2029			
Benefits	1057.092	659.737	1477.708
Costs	182.265	160.84	202.853
Transfers	36.439	28.775	45.827
Net Benefits	874.827	481.867	1287.256
2030			
Benefits	1085.055	680.607	1506.937
Costs	185.26	169.543	203.835
Transfers	37.038	29.646	46.302
Net Benefits	899.795	498.646	1316.680
2031			
Benefits	1095.782	687.308	1521.884
Costs	185.26	169.543	203.835
Transfers	37.038	29.646	46.302
Net Benefits	910.522	505.341	1331.612
2032			
Benefits	1106.616	694.074	1536.981
Costs	185.26	169.543	203.835
Transfers	37.038	29.646	46.302
Net Benefits	921.356	512.108	1346.693
2033			
Benefits	1117.558	700.9	1552.229
Costs	185.26	169.543	203.835
Transfers	37.038	29.646	46.302
Net Benefits	932.298	518.943	1361.925
2034			
Benefits	1128.609	707.794	1567.630
Costs	185.26	169.543	203.835
Transfers	37.038	29.646	46.302
Net Benefits	943.349	525.865	1377.309

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 13. Present Value and Annualized Impacts

	Mean	p5	p95
Present Value of Benefits	8083.468	5040.186	11329.769
Health Benefits, Kidneys	3400.571	2022.686	4982.786
Health Benefits, Livers	4590.601	2878.807	6382.815
Time-Saving Benefits	92.297	72.379	116.703
Present Value of Costs	1379.268	1207.047	1559.128
Present Value of Transfers	275.653	216.165	348.544
Present Value of Net Benefits	6704.2	3700.52	9891.249
Annualized Benefits	899.904	561.106	1261.304
Health Benefits, Kidneys	378.574	225.179	554.716
Health Benefits, Livers	511.056	320.488	710.577
Time-Saving Benefits	10.275	8.058	12.992
Annualized Costs	153.549	134.376	173.572
Annualized Transfers	30.688	24.065	38.802
Annualized Net Benefits	746.355	411.966	1101.158

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.

Alternate Study for Transplant Impacts under the Proposed Rule

Our main analysis is based on a study reporting estimates of 192 kidneys and 247 livers from deceased organ donors who had HIV.[62] After accounting for several adjustments to these estimates related to the deceased organ donation consent rate, size of the deceased donor pool, and living donors, as discussed in Section II.D, and subtracting transplants occurring under the baseline scenario, we reported that the proposed rule would result in an additional 100 kidney and 177 liver transplants per year once the policy effects fully materialize, with primary estimates of the yearly impacts reported in Table 2.

Section II.D also identifies another study[63] with higher estimates: 63 kidney-only donors, 221 liver-only donors, and 250 kidney and liver donors. These findings correspond to 313 kidneys and 471 livers available for transplantation if each deceased donor yielded an average of 1 recovered organ by type, or 435 kidneys and 471 livers adopting an alternative assumption that 1.39 kidneys are recovered and transplanted per deceased kidney donor.[64] As a sensitivity analysis, we recalculated the impacts of the proposed rule, basing our estimates on the conclusions of the alternate study. After applying the same adjustments and accounting for transplants occurring under the baseline scenario, this sensitivity analysis indicates the proposed rule would result in an additional 349 liver transplants per year, and between 201 and 303 kidney transplants per year, depending on the assumed number of kidneys recovered per deceased

[62] 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.
[63] 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.
[64] 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.

donor. Thus, this sensitivity analysis indicates that adopting estimates from the alternate study would increase the magnitude of the benefits and costs associated with liver transplants by 97%[65] relative to the impacts of our main analysis. Adopting this study would also increase the annual magnitude of the benefits, costs, and transfers associated with kidney transplants by 101% to 204%, depending on the assumed number of kidneys recovered per deceased donor.

I. Distributional Effects

Section B 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 would be realized by recipients living with HIV receiving organs with HIV as a direct result of the proposed rule, but also by recipients without HIV receiving donor organs without HIV through reduced waiting times.

Section D of the NPRM'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 proposed 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 proposed rule.

III. **Initial Small Entity Analysis**

The Regulatory Flexibility Act (RFA) requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the impacts are small relative to the number of organ transplants performed annually, and because the costs are small relative to the annual payroll of firms in the smallest enterprise size category, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The SBA maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).[66] We replicate the SBA's description of this table:

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[65] 349/177 ≈ 1.97.

[66] U.S. Small Business Administration (2023). "Table of Size Standards." March 17, 2023 https://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.

This proposed rule would likely impact 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.[67] We tentatively 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 14 presents statistics for kidney dialysis centers by enterprise size, including the annual payroll per firm.

Table 14. 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

This proposed rule would also likely impact the 247 organ transplant centers identified in section C of this analysis. 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

[67] 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 using annual figures of CPI-U. U.S. Bureau of Labor Statistics. CPI for all Urban Consumers (CPI-U), Not Seasonally Adjusted, https://data.bls.gov/timeseries/CUUR0000SA0.

this NAICS category.[68] We tentatively conclude, based on the annual payroll per firm in the enterprise size categories, that almost all organ 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 organ transplant centers are likely small entities due to not-for-profit status. Table 15 presents statistics for general medical and surgical hospitals by enterprise size, including the annual payroll per firm.

Table 15. 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 Potential Impacts of the Rule on Small Entities

In 2020, the prevalent count of individuals receiving in-center hemodialysis was 480,516.[69] We estimate that the proposed rule, if finalized, would reduce the number of individuals receiving dialysis by about 100 per year. This impact would represent a change of about 0.02% of all dialysis patients, and would likely have a similar impact, measured as a proportion of revenue, for kidney dialysis centers that are small entities. In the context of the RFA, HHS generally considers a 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 proposed rule will not have a significant economic impact on a substantial number of kidney dialysis centers that are small entities.

Section F of this analysis identifies costs associated with reading and understanding the rule, reviewing policies and procedures, and training staff. Across firms of all sizes, the average total costs are $4,891 per transplant center. We next compare these costs to the average payroll of

[68] 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 using annual figures of CPI-U. U.S. Bureau of Labor Statistics. CPI for all Urban Consumers (CPI-U), Not Seasonally Adjusted, https://data.bls.gov/timeseries/CUUR0000SA0.

[69] 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.

firms in the smallest enterprise size reported in Table 15. General medical and surgical hospitals with fewer than 5 employees have an annual payroll per firm of $316,049. The average total costs per transplant center are about 1.5% of this annual payroll, which is below the threshold for a significant impact. Further, we expect that most, if not all, transplant centers fall into larger enterprise size categories, and thus the costs would represent a smaller share of annual payroll. Therefore, this analysis concludes that the proposed rule will not have a significant economic impact on a substantial number of organ transplant centers that are small entities.

IV. **References**

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