imposed by State law. Therefore, this action is not subject to review by OMB. This action is not an Executive Order 13771 (82 FR 9339, February 3, 2017) regulatory action because actions such as today's proposed authorization of Maine's revised hazardous waste program under RCRA are exempted under Executive Order 12866. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action proposes to authorize pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to authorize State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in proposing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of this action in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). ''Burden'' is defined at 5 CFR 1320.3(b). Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this action proposes authorization of pre-existing State rules which are at least equivalent to, and no less stringent than existing federal requirements, and imposes no additional requirements beyond those imposed by State law, and there are no anticipated significant adverse human health or environmental effects, this proposed rule is not subject to Executive Order 12898.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: November 12, 2019.

Dennis Deziel,

Regional Administrator, Region 1.

[FR Doc. 2019–27273 Filed 12–19–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

RIN 0906–AB23

Removing Financial Disincentives to Living Organ Donation

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to amend the regulations implementing the National Organ Transplant Act of 1984, as amended (NOTA), to remove financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages and child-care and elder-care expenses incurred by a primary care giver. HHS is committed to reducing the number of individuals on the organ transplant waiting list by increasing the number of organs available for transplant. This proposed rule implements Section 8 of the Executive Order (E.O.) on Advancing American Kidney Health, issued on July 10, 2019, which directs HHS to propose a regulation allowing living organ donors to be reimbursed for related lost wages, child-care expenses, and elder-care expenses through the Reimbursement of Travel and Subsistence Expenses Incurred toward Living Organ Donation program.

DATES: Written comments and related material to this proposed rule must be received to the online docket via *www.regulations.gov,* or to the mail address listed in the **ADDRESSES** section below, on or before February 18, 2020.

ADDRESSES: You may submit comments on this proposed rule identified by HHS Docket No. HRSA–2019–0001, by any one of the following methods:

- *Federal eRulemaking Portal (preferred): www.regulations.gov.* Follow the website instructions for submitting comments.
- *Mail:* Alford Danzy, Regulations Officer, Executive Secretariat, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Room 13N82, MD 20857. To ensure proper handling, please reference HHS Docket No. HRSA–2019–0001 in your correspondence. Mail must be postmarked by the comment submission deadline.

FOR FURTHER INFORMATION CONTACT: Frank Holloman, Director, Division of Transplantation, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W63, Rockville, MD 20857; by

email at *donation@hrsa.gov;* or by telephone (301) 443–7577.

SUPPLEMENTARY INFORMATION:

I. Public Participation

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

Instructions: If you submit a comment, you must include the agency name and the HHS Docket No. HRSA–2019–0001 for this rulemaking. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make to HHS. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Docket: For access to the docket and to read background documents or comments received, go to *http://regulations.gov,* referencing HHS Docket No. HRSA–2019–0001. You may also sign up for email alerts on the online docket to be notified when comments are posted or a final rule is published.

II. Background and Purpose

As of January 2019, more than 113,000 men, women, and children were on the national organ transplant waiting list. Every 10 minutes another person is added to the waiting list, and approximately 20 people die every day while waiting for a transplant.[1] The current approach to acquiring organs for transplantation relies on the altruism of deceased donors and families and the voluntarism and altruism of living organ donors. Living organ donation is an important option for thousands of men, women, and children on the national transplant waiting list. Transplants using organs from living donors accounted for 19 percent (6,849) of the total (36,528) transplants performed in 2018.[2] Transplants involving organs from deceased donors, who can provide multiple organs, comprised the other 81 percent (29,680) of the 2018 total.[3]

Living organ donation offers a viable transplant option, primarily for kidney and liver transplant candidates, and helps to reduce the overall number of individuals on the deceased donor organ waiting list, improving the transplantation system. The President's Executive Order on Advancing American Kidney Health emphasized that supporting living organ donors can help address the current demand for kidney transplants. That Executive Order directed the HHS Secretary to propose a regulation that would expand the definition of allowable costs that can be reimbursed under HRSA's current Reimbursement of Travel and Subsistence Expenses Incurred toward Living Organ Donation program. This NPRM aligns with the aforementioned Executive Order, which also included language to specifically allow for the reimbursement of lost wages along with child-care and elder-care expenses.

Living organ donation also delivers a number of other benefits for the recipient. The living organ donor transplant recipient can often receive a better quality organ in a shorter time period, which often results in lower rates of graft failure and improved survival rates for organ recipients.[4] In general, recipients of kidney transplants from living organ donors have better clinical outcomes than those who continue on dialysis or receive a deceased donor kidney transplant.[5] Living organ donation also provides significant cost savings over the course of a recipient's lifetime. In the first five years alone following their transplants, projected return on investment (ROI) for living donor financial assistance, relative to dialysis versus transplant costs, has been shown to provide 5.1-fold ROI in year 1 rising up to 28.2-fold ROI in year 5, and produces $256.4 million in savings against patients having remained on dialysis.[6] Living organ donations also deliver intangible benefits, such as the positive feelings that can come with saving or improving the life of another individual. All such benefits must be weighed against the donor risks, which include surgical and anesthesia-related complications and infections as well as the uncertainty of the long-term health effects on donors following living organ donation, which are currently being studied.

According to the 2017 U.S. Scientific Registry of Transplant Recipients (SRTR) Annual Data Report, between 4,400 and 5,000 adults awaiting kidneys are removed from the national transplant waiting list every year because they have died, and an additional 4,000 to 4,500 are removed because they have become too sick to receive a transplant.[7] As of 2016, there were over 500,000 individuals receiving dialysis treatment, and over 200,000 lived with a kidney transplant.[8] To date, approximately 96,000 of these individuals are on the national waiting list awaiting an available kidney.[9] As such, the agency believes regulatory changes designed to increase living organ donation, by removing financial disincentives for living organ donors, such as those proposed in this rule, could mitigate some of these tragic outcomes. The agency further believes that this regulatory language, if finalized as proposed, will encourage and allow for more potential living organ donors to proceed to donation.

A. HRSA's Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation Program

Congress provided specific authority under section 377 of the Public Health Service (PHS) Act, as amended, 42 U.S.C. 274f,[10] to the Secretary of Health and Human Services (the Secretary) for reimbursement of travel and subsistence expenses, which encompasses costs for travel to medical and clinical appointments, lodging, and meals, incurred by eligible individuals making living donations of their organs, and

[1] Information from *https://www.organdonor.gov/statistics-stories/statistics.html#glance* and accessed on August 26, 2019.

[2] Data from *optn.transplant.hrsa.gov* and OPTN/SRTR Annual Report.

[3] Data from *optn.transplant.hrsa.gov* and OPTN/SRTR Annual Report.

[4] Data from *https://srtr.transplant.hrsa.gov/annual_reports/2017/Kidney.aspx.*

[5] Data from *https://srtr.transplant.hrsa.gov/annual_reports/2017/Kidney.aspx.*

[6] Mathur AK et al. Return on investment for financial assistance for living kidney donors in the United States. *Clinical Transplant.* 2018;32:e13277. *https://doi.org/10.1111/ctr.13277.*

[7] Data obtained from *https://srtr.transplant.hrsa.gov/annual_reports/2017/Kidney.aspx#KI_5_activity_adult_waiting.*

[8] Data obtained from *https://www.kidney.org/news/newsroom/factsheets/KidneyDiseaseBasics.*

[9] Data obtained from *https://optn.transplant.hrsa.gov/data/* and accessed on September 23, 2019.

[10] Information obtained from *https://www.govinfo.gov/content/pkg/PLAW-108publ216/pdf/PLAW-108publ216.pdf.*

other individuals accompanying the living organ donors.

Within the same section of the PHS Act, Congress also authorized the Secretary to reimburse ''incidental non-medical expenses'' incurred by living organ donors under 42 U.S.C. 274f(a)(2), if the Secretary determines by regulation that reimbursements for such expenses is appropriate.

The National Living Donor Assistance Center (NLDAC) is the living donor reimbursement program (*https://www.livingdonorassistance.org/home/default.aspx*) funded by HRSA's Reimbursement of Travel and Subsistence Expenses Incurred toward Living Organ Donation grant's program. Pursuant to the authority provided under section 377 of the PHS Act, as amended, in 2006 HRSA initially awarded a cooperative agreement to the Regents of the University of Michigan, which partnered with the American Society of Transplant Surgeons to establish the NLDAC in order to operate a program to provide this type of reimbursement. In May 2016, the cooperative agreement transferred to the University of Arizona and in 2019, a new award was granted to the University of Arizona. The program's purpose is to help remove financial disincentives for living organ donations. In adherence to the authority outlined in the PHS Act, the Program Guidelines for NLDAC provide that ''qualifying expenses'' include those incurred by the donor and/or his/her accompanying person(s) as part of: (1) Donor evaluation and/or (2) hospitalization for the living donor surgical procedure, and/or (3) medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure.[11] It is important to note that not all applicants or recipients of reimbursements will go on to donate an organ. Many factors may prevent an intended and willing donor from proceeding with the donation. Such circumstances include present health status of the intended donor or recipient that would prevent the transplant or donation from proceeding, perceived long-term risks to the intended donor, or unforeseen events outside the intended donor's control.

The criteria for reimbursement are based on the incomes of both the recipient and potential living organ donor and include only the aforementioned qualifying expenses. As such, NLDAC currently does not reimburse other expenses incurred by the donor, such as lost wages or child-care and elder-care expenses. Under federal law, the NLDAC cannot reimburse any living organ donor for travel and other qualifying expenses if the donor can be reimbursed for these expenses from any of the following sources: (1) Any state compensation program, an insurance policy, or any federal or state health benefits program; (2) an entity that provides health services on a prepaid basis; or (3) the recipient of the organ. HRSA notes that some living organ donors may receive assistance from other sources, such as private insurers' programs; however, HRSA's reimbursement program specifically aims to assist lower-income donors who lack other forms of financial support. The Program was designed to be the payer of last resort and does not provide funds as a gift or reward to individuals for being a donor.

As intended by HRSA and in compliance with the authorizing legislation, NLDAC prioritizes lower-income donors who are highly unlikely to secure funds for non-medical donation-related expenses from any other sources, and excluded donors when the recipients could reasonably be expected to pay for such expenses. From September 1, 2014, to January 31, 2019, NLDAC received and processed over 3,300 applications, approving nearly 2,900 (87.5 percent). Over that 5-year period, the median household income of NLDAC donors and recipients was $35,229 and $27,519, respectively. The average NLDAC reimbursement in fiscal year 2018 was $1,934 per donor among 1,055 donor applications.

Currently, the median household incomes of NLDAC donors and recipients both fall below the 40th percentile of American households.[12] The strongest evidence that NLDAC is meeting the needs of donors facing financial barriers to donation is demonstrated by data supplied by the current grantee showing that the median household income among NLDAC donors in fiscal year 2018 was $35,463, which is significantly lower than that for other U.S. donors $46,870.

If these changes are finalized as proposed, based on preliminary information provided by the grantee, the agency projects a four to six-fold increase in the number of applicants to the NLDAC. The agency also projects that there would be a subsequent increase in the number of transplants facilitated by NLDAC, commensurate with appropriated funding levels and recipient eligibility guidelines.

The Secretary has not previously determined by regulation that reimbursement for any categories of ''incidental non-medical expenses'' incurred by living organ donors toward their living organ donations may appropriately be provided. If these regulatory changes become final, the agency would amend the Program's Guidelines to reflect inclusion of the specified additional expenses determined to be appropriate for reimbursement.

B. Executive Order 13879: Advancing American Kidney Health

In the E.O on Advancing American Kidney Health, issued on July 10, 2019, the President directed HHS to propose a regulation to allow living donors to be reimbursed for related lost wages, child-care expenses, and elder-care expenses through the Reimbursement of Travel and Subsistence Expenses Incurred toward Living Organ Donation program authorized by 42 U.S.C. 274f. This proposed rule fulfills the President's mandate.

The E.O. further directed HHS to propose a raise to the limit on the income of living donors eligible for reimbursement under the program. The limit on donor income is set through the reimbursement program's Eligibility Guidelines. HRSA is proposing a revision to the Eligibility Guidelines and is considering increasing the upper threshold for living organ donor and organ recipient household income. HRSA will seek public comment on this planned revision to the Eligibility Guidelines through a separately published **Federal Register** notice. Therefore, this proposed rule does not address that aspect of the Executive Order. HRSA will further revise the Eligibility Guidelines to reflect any changes to the reimbursement program made through this rulemaking process.

C. Advisory Committee on Organ Transplantation Recommendations

Section 121.12 of the OPTN Final Rule established the Advisory Committee on Organ Transplantation (ACOT). ACOT advises and provides recommendations to the Secretary through HRSA on:

- All aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines;
- federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation;

[11] NLDAC program guidelines are available at *https://www.govinfo.gov/content/pkg/FR-2009-06-19/pdf/E9-14425.pdf.*

[12] According to the 2013–2017 U.S. Census Bureau American Community Survey 5-Year Estimates, the median household income is $57,652. Data is available at *https://www.census.gov/programs-surveys/acs/.*

- the latest advances in the science of transplantation; and,
- at the request of the Secretary, significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable.

In May 2019, ACOT voted to provide recommendations to the Secretary which, if adopted, would increase access to organs from living organ donors by providing living donors with additional support and resources and by removing disincentives that may have prevented potential donors from donating. Two of these recommendations are:

- Encourage a permanent mechanism for lost wages reimbursement for non-directed living donors in conjunction with the travel and subsistence costs.
- Amend current guidelines to improve reimbursement so that it includes reimbursement for living donors' child-care and elder-care expenses in addition to travel and subsistence costs.

D. Section 301 of NOTA

Reimbursement payments received via NLDAC must not violate section 301 of NOTA, which makes it ''unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce,'' as described in 42 U.S.C. 274e(a). Thus, section 301 of NOTA outlaws the purchase and sale of organs. Certain expenses are specifically excluded from the scope of valuable consideration, including ''expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.'' 42 U.S.C. 274e(c)(2). Section 301 of NOTA does not expressly say whether child-care or elder-care expenses incurred by a donor in connection with the donation constitute prohibited ''valuable consideration.'' HHS has determined, and the U.S. Department of Justice, Office of Legal Counsel, concurred, that the reimbursement of child-care and elder-care expenses as described here are not valuable consideration under section 301 of NOTA. Therefore, this prohibition does not pose a barrier to the Secretary determining by regulation that the reimbursement of such expenses is appropriate under the authority provided by 42 U.S.C. 274f(a)(2).

III. Discussion of Proposed Rule

Abstract research data showed that, when asked, 75.6 percent of living donors who received NLDAC funds stated that they would not have been able to donate a kidney without the financial assistance provided by the program.[13] In line with this finding, the Agency believes that there are many potential living organ donors who would like to donate an organ to a family member or friend, but cannot afford the loss of income incurred during the required weeks out of work needed for the transplant surgery and recovery time. The extended recovery time can also adversely impact potential donors who are the primary caregivers for children and/or elderly family members. Potential donors can face challenges paying for indirect expenses related to transplantation not covered by insurance. Overall, the costs of the process can be a burden for donors and recipients; for some, these costs make living organ donation unlikely or even impossible.

HRSA's reimbursement program, which is operated through NLDAC, does not currently reimburse lost wages or child-care or elder-care expenses. As previously discussed, section 301 of NOTA is not a barrier to the Secretary determining, by regulation, that such expenses may be reimbursed. Accordingly, HRSA is proposing to remove barriers and disincentives to living organ donation by amending the OPTN Final Rule to formally add lost wages child-care and elder-care expenses incurred by primary caregivers as reimbursable expenses for living organ donors. This rule, if finalized as proposed, will constitute the Secretary's determination by regulation that reimbursement may be appropriately provided for lost wages, and child-care and elder-care expenses incurred by primary caregivers who make living donations of their organs, as authorized by section 377(a)(2) of the PHS Act. HRSA proposes adding a new regulatory section at § 121.14 to list the categories of ''incidental non-medical expenses'' that the Secretary has determined are appropriate for reimbursement.

The other criteria of HRSA's reimbursement program, as provided in the program's Eligibility Guidelines, remain applicable and will still need to be met for reimbursement to be provided to living donors and other individuals evaluated for living organ donation for lost wages and child-care and elder-care expenses incurred by primary caregivers while making donations of their organs. Once the final rule is published, HRSA will revise the Eligibility Guidelines to specifically address reimbursement criteria for these reimbursable expenses.

A. Lost Wages

Many potential living organ donors may be willing and available to donate an organ to a family member, friend, or an unknown recipient, but would be unable to afford the loss in income while out of work during the transplant process, which includes the pre-transplant evaluation, surgery, subsequent recovery time, and follow-up appointments. This proposed rule would remove this potential barrier to living organ donations. In amending the OPTN Final Rule, HRSA proposes determining lost wages as an appropriate reimbursable expense for living organ donors, and adding lost wages as a category of reimbursable incidental non-medical expenses at § 121.14(a)(1).

B. Child-Care Expenses and Elder-Care Expenses

Included among the many costs associated with living organ donation are, for many individuals, the costs of child-care and elder-care. Such costs can be incurred throughout the organ donation process, from the transplant pre-evaluation through the hospital stay, during the recovery period, and while the living donor attends necessary follow-up medical appointments. This proposed rule would remove financial barriers to living organ donation by expanding allowable reimbursements to include child-care and elder-care expenses. Through this proposed rule, HRSA proposes determining that child-care and elder-care expenses incurred by primary caregivers are appropriate reimbursable expenses for living organ donors, and adding child-care expenses at § 121.14(a)(3) and elder-care expenses at § 121.14(a)(4) as categories of reimbursable incidental non-medical expenses.

Additional Financial Barriers to Organ Donation

Similar to the consideration of the wages lost by a potential living organ donor, HRSA is concerned about other financial barriers to organ donation, including but not limited to challenges related to employer-provided medical insurance benefits while out of work during the transplant process, including pre-transplant donor evaluation, donor surgery, and post-surgery recovery. These challenges could include ''foregone medical insurance benefits,'' defined as the loss of a wage supplement for medical insurance premiums provided by an employer.

[13] Merion RM et al. Analysis of dialysis cost and median waiting time on return on investment (ROI) of the US National Living Donor Assistance Center (NLDAC) program [abstract]. *Transplantation.* 2016;100:S310.

HRSA specifically seeks public comment on this descriptor and any literature or evidence on additional financial barriers to organ donation, including whether foregone medical insurance benefits pose a significant barrier to organ donation. While HRSA is not proposing that foregone medical insurance benefits are an appropriate reimbursable expense for living organ donors in this rulemaking, we are interested in public comment as to whether, in a future rulemaking, we should consider any additional benefits as categories of reimbursable incidental non-medical expenses.

IV. Statutory and Regulatory Requirements

A. Executive Orders 12866, 13563, and 13771: Regulatory Planning and Review

HHS has examined the effects of this proposed rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), and E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

E.O. 12866 and E.O. 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 supplements and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866, which emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Section 3(f) of E.O. 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). This proposed rule has been determined to be a significant regulatory action. Accordingly, the proposed rule has been reviewed by OMB.

E.O. 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' The designation of this rule, if finalized, will be informed by public comments received; however, if finalized as proposed, this rule would be neither regulatory nor deregulatory for purposes of E.O. 13771. There are no additional costs; the proposed rule, if finalized, will only change how HRSA expends the appropriated funds.

Summary of Impacts

Research into similar legislative changes and changes to financial incentives have demonstrated increases in organ donations; thus, the agency estimates that these proposed regulatory changes will increase the number of living organ transplants. The agency expects this increase for two primary reasons. Studies have shown that reimbursement measures have increased organ donations anywhere from 14 percent to 65 percent, depending on the particular circumstances of the study, and secondly, donor income also appears to play a role in living organ donor transplant rates.

While specific details vary, the country of Israel's move toward reimbursing lost wages and providing other benefits yielded a 65 percent increase in kidney transplants from living donors.[14] In the United States, paying donation-related travel costs through NLDAC increased the number of living donor kidney transplants by approximately 14 percent,[15] with a separate survey of NLDAC donors revealing that 75 percent of donors would not have donated without reimbursement.[16] In addition, tax incentive legislation in New York increased living kidney donations to non-family members by 52 percent.[17] Finally, a study looking at longitudinal trends found that income was strongly associated with donation, with higher rates of donation observed in higher income populations and donation rates declining among the lowest earners after the last recession.[18]

Currently, the United States averages approximately 6,500 living organ donations per year. Determining how many of these, or any additional, living organ donors will be eligible for the proposed financial incentives involves the interplay of a number of factors, as does calculating the cost of these incentives.

First, not all living donors will be eligible for these reimbursements. As previously stated, the E.O. on Advancing American Kidney Health also directed HHS to propose raising the limit on the income of living donors eligible to be reimbursed under the program. The income eligibility threshold is the first criterion in determining whether a potential donor is eligible to receive reimbursement of expenses incurred. Additionally, as previously outlined, NLDAC is to be used as the payer of last resort and cannot reimburse qualifying expenses if the living organ donor can be reimbursed for these expenses through other means.

Second, not all program-eligible living organ donors will incur expenses relating to each one of the new categories of reimbursements (lost wages, child-care, elder-care) offered through the regulatory change. Each donor's circumstances differ; some might request reimbursement for all three types of added reimbursable expenses, some for one or two, and some for none at all.

Third, donors' specific circumstances will determine the reimbursable amounts. Individual wages differ, as do the type, level, and amount of child-care and/or elder-care required to

[14] Lavee, J., Ashkenazi, T., Stoler, A., Cohen, J., & Beyar, R. (2012). Preliminary Marked Increase in the National Organ Donation Rate in Israel Following Implementation of a New Organ Transplantation Law. *American Journal of Transplantation,*13 (3), 780–785, 2012. doi:10.1111/ajt.12001.

[15] Schnier, K.E., Merion, R.M., Turgeon, N., & Howard, D. (2018). Subsidizing altruism in living organ donation. *Economic Inquiry, 56*(1), 398–423.

[16] Merion RM et al. Analysis of dialysis cost and median waiting time on return on investment (ROI) of the US National Living Donor Assistance Center (NLDAC) program [abstract]. *Transplantation.* 2016;100:S310.

[17] Bilgel, F., & Galle, B. (2015). Financial incentives for kidney donation: A comparative case study using synthetic controls. *Journal of Health Economics.* 43, 103–117.

[18] Gill, J., Dong, J., Rose, C., Johnston, O., Landsberg, D., & Gill, J. (2013). The effect of race and income on living kidney donation in the United States. *Journal of the American Society of Nephrology.* 24(11), 1872–1879.

compensate those donors who are caregivers.

Fourth, while living organ donors typically face a 4–6 week post-surgical recovery time, individual recovery times will vary. Surgical complications or personal health issues might slow that process, and the physical demands of the donor's work (*i.e.,* strenuous versus sedentary) might dictate how quickly she or he can return to work.

Given these individual differences, HRSA is using median weekly figures for each expense to estimate the expected costs per individual of these regulatory changes. Please note that the lost wages category correlates to a typical 40-hour work week, while child-care and elder-care are extrapolated out to a full 7-day week, on the presumption that caregivers will require assistance caring for children and the elderly on the weekends as well.

- Wages: $28 per hour [19] for 40 hours per week is a weekly average wage of $1,120 per week or $4,480–$6,720 over 4–6 weeks.
- Child-care: At $420 per full week [20] child-care will cost $1,680–$2,520 over 4–6 weeks.
- Elder-care: At $504 per full week [21] elder-care will cost $2,016–$3,024 over 4–6 weeks.

Funding for this program is a fixed amount that is determined through annual federal discretionary appropriations. These regulatory changes will result in expanded coverage and a potential increase in user demand of the living organ donor reimbursement program. Expanding the list of eligible expenses could increase the average reimbursement. The number of individuals receiving reimbursement and/or the amount of reimbursements per individual in any given fiscal year will be dependent upon annual appropriations. Therefore, increases in the average reimbursement without increases in appropriations could result in fewer individuals being served by the program. Based on the uncertainty of annual appropriation levels for the program, HRSA is considering a range of methods to ensure the ongoing viability of this program, such as a reimbursement cap.

In relation to caps on reimbursements, under current program guidelines, NLDAC limits donors to a maximum of $6,000 for reimbursement of solely travel and subsistence; a correlating demonstration project, on lost wages, limits reimbursement of solely lost wages to a maximum of $5,000; donors receiving reimbursements from both programs are capped at receiving a combined maximum of $8,000. In fiscal year 2018, the average NLDAC reimbursement was $1,934 per donor, which is lower than the current cap level. HRSA may adjust the cap to account for lost wages, child-care, and elder-care. HRSA acknowledges that this cap may not cover the entirety of reimbursable expenses incurred by some donors; however, this assistance does align with one of the major goals of the reimbursement program: To reduce financial disincentives and disparities, not to necessarily make donors whole financially.

While expanding the list of expenses eligible for reimbursement for living organ donors will increase the average amount of reimbursement, the federal government can expect to save overall due to an increase in additional organ transplants performed and the aversion of dialysis. The costs/savings incurred by kidney transplantation vary by donor type. One study using Medicare claims data [22] estimated End-Stage Renal Disease (ESRD) expenditures to be $292,117 over 10 years per beneficiary on dialysis. Living donor kidney transplants (LDKT) was cost-saving at 10 years, reducing expected medical expenditures for ESRD treatment by 13 percent ($259,119) compared to maintenance dialysis.

The approximately $33,000 in Medicare savings per beneficiary over 10 years for LDKT compared to maintenance dialysis is likely a lower bound, since living donation would help reduce the number of beneficiaries under the age of 65 who would be eligible for Medicare enrollment. The lower bound conditional savings can be adjusted to account for additional savings through reduced Medicare enrollment by considering the share of potential new live donations across three main scenarios.

The LDKT expected cost of $259,119 over 10 years per beneficiary projected by Axelrod et al. (2018) assumes Medicare primary payer status. For roughly 25 percent of LDKTs, Medicare is assumed as the primary payer regardless of transplant success; therefore, the projected spending need not be adjusted. For the next 25 percent of LDKTs, the assumption was that the beneficiary is on dialysis and Medicare is the primary payer, but they would eventually no longer need dialysis and/or leave Medicare enrollment if they had a transplant, and are not otherwise eligible for Medicare due to age or disability. Therefore, the expected Medicare spending for these cases was adjusted downward by 33 percent. This projected a savings of approximately $119,000 over 10 years relative to the baseline spending projection of $292,117 over 10 years for beneficiaries on dialysis. For the remaining 50 percent of LDKTs—it was assumed that Medicare is not the primary payer when the transplant occurs. In this case, it was assumed that Medicare spending is nominal relative to baseline spending of $292,117 over 10 years for beneficiaries on dialysis, and amounts were adjusted downward by 33 percent (that is, for these beneficiaries, Medicare would have become the primary payer 30 months to become a Medicare primary payer enrollee absent the transplant), which projected a savings of approximately $195,000 over 10 years. The projected weighted average federal budgetary savings to the Medicare program for LDKT is $136,000 over 10 years per beneficiary.

Therefore, a hypothetical 20 percent increase in the rate of LDKT in model markets in a single year, representing about 500 new kidney transplants mainly from relatives of recipients, would produce approximately $68 million in federal budgetary savings to the Medicare program over 10 years (and multiples thereof for each successive year if the living donor kidney transplant rate was thusly elevated). Overall, having more end stage renal disease (ESRD) individuals receiving transplants will ultimately decrease Medicare expenditures.[23]

A. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and

[19] Information from the U.S. Bureau of Labor Statistics and available at *https://www.bls.gov/news.release/empsit.nr0.htm.*

[20] National Center for Education Statistics and available at *https://nces.ed.gov/programs/digest/d18/tables/dt18_202.30c.asp.*

[21] Paying for senior care, *https://www.payingforseniorcare.com/longtermcare/costs.html#Non-Medical-Home-Care.*

[22] Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. *Am J Transplant.* 2018;18:1168–1176. *https://doi.org/10.1111/ajt.14702.*

[23] Obtained from proposed rule CMS–5527–P *Specialty Care Models to Improve Quality of Care and Reduce Expenditures* posted on July 18, 2019, and information available at *https://www.federalregister.gov/documents/2019/07/18/2019-14902/medicare-program-specialty-care-models-to-improve-quality-of-care-and-reduce-expenditures.*

analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities. HHS has determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small manufacturers; therefore, we are not preparing an analysis of impact for the purposes of the RFA.

B. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' In 2019, that threshold is $154 million. HHS does not expect this proposed rule to exceed the threshold.

C. Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have ''federalism implications.'' This proposed rule would not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

D. Collection of Information

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This proposed rule is projected to have no impact on current reporting and recordkeeping burden, as the amendments proposed in this rule will not impose any data collection requirements under the PRA.

List of Subjects in 42 CFR Part 121

Health care, Hospitals, Transplant Centers, Organ Transplantation Reporting and recordkeeping requirements.

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

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

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

■ 2. Revise § 121.1 to read as follows:

§ 121.1 Applicability.

(a) The provisions of this part, with the exception of §§ 121.13 and 121.14, apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) The provisions of § 121.13 apply to the prohibition set forth in section 301 of the National Organ Transplant Act, as amended.

(c) The provisions of § 121.14 apply to the reimbursement of specified incidental non-medical expenses incurred toward living organ donation under section 377 of the Public Health Service Act, as amended.

(d) In accordance with section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.

■ 3. Add § 121.14 to read as follows:

§ 121.14 Reimbursement for Living Organ Donors: Incidental Non-Medical Expenses.

(a) The following incidental non-medical expenses incurred by donating individuals toward making living donations of their organs may be reimbursed:

(1) Lost wages;

(2) Child-care expenses; and

(3) Elder-care expenses.

(b) [Reserved]

Dated: December 16, 2019.

Thomas J. Engels,

Administrator, Health Resources and Services Administration.

Approved: December 16, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–27532 Filed 12–17–19; 4:15 pm]

BILLING CODE 4165–15–P