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## 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), Health and Human Services Department (HHS).

**ACTION:** Final rule.

**SUMMARY:** This final rule amends 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 caregiver. 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 final rule is associated with Section 8 of the Executive Order (E.O.) 13879 titled ''Advancing American Kidney Health,'' issued on July 10, 2019, which directed 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 authorized under section 377 of the Public Health Service (PHS) Act, as amended.

**DATES:** This final rule is effective on October 22, 2020.

**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

On December 20, 2019, HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (84 FR 70139) to amend the regulations implementing the NOTA to remove financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors. The NPRM provided for a 60-day comment period, and HHS received 267 comment letters raising a variety of issues. HHS has carefully considered all comments in developing this rule, as outlined in Section V below, and presents a summary of all significant comments and Departmental responses.

### II. Background

As discussed in the NPRM, every 10 minutes, another person is added to the national organ transplant 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 their families and the voluntarism and altruism of living organ donors.

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 national organ transplant waiting list, thus improving the transplantation system overall. The President's E.O. 13879, ''Advancing American Kidney Health,'' emphasized that supporting living organ donors can help address the current demand for kidney transplants. That E.O. 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 final rule addresses this E.O. requirement, which also included language specifically addressing reimbursement of lost wages along with child-care and elder-care expenses.

Living organ donation also delivers several additional benefits for the recipient, as described in the NPRM, including receipt of a better quality organ in a shorter time period and better clinical outcomes than those who continue on dialysis or receive a deceased donor kidney transplant.[2] However, 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.

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

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

#### *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,[3] 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 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 are appropriate.

The National Living Donor Assistance Center (NLDAC)[4] operates the living organ donor reimbursement program funded by HRSA's Reimbursement of Travel and Subsistence Expenses Incurred toward Living Organ Donation grants program. Under the authority provided under section 377 of the PHS Act, as amended, the program is operated via cooperative agreement. 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's Eligibility Guidelines currently provide that ''qualifying expenses'' include those incurred by the donor and his/her accompanying person(s) as part of: (1) Donor evaluation, (2) hospitalization for the living donor surgical procedure, and/or (3) medical or surgical follow-up, clinic visits, or hospitalization within two calendar years following the living donation procedure.[5] 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.

[3] Available at *https://www.govinfo.gov/content/pkg/PLAW-108publ216/pdf/PLAW-108publ216.pdf.*

[4] The Center's website is available at *https://www.livingdonorassistance.org/home/default.aspx.*

[5] The Eligibility Guidelines for HRSA's reimbursement program are available at *https://www.govinfo.gov/content/pkg/FR-2009-06-19/pdf/E9-14425.pdf.*

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. Under federal law, HRSA's reimbursement program 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.

Through this final rule, the Secretary determines that reimbursement for lost wages, and child-care and elder-care expenses incurred by a caregiver, is appropriate for living organ donors who incur such expenses toward their organ donation.

*B. Executive Order 13879: Advancing American Kidney Health*

In E.O. 13879, ''Advancing American Kidney Health,'' issued on July 10, 2019, the President directed HHS to propose a regulation to allow 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 authorized by 42 U.S.C. 274f. This final rule aligns with the goals of the President's mandate.

The E.O. further directed HHS to raise the limit on the income of living organ donors eligible for reimbursement under the program. The limit on donor income is set through the reimbursement program's Eligibility Guidelines. HRSA has proposed a revision to the Eligibility Guidelines increasing the upper threshold for living organ donor and organ recipient household income from 300 percent to 350 percent of the HHS Poverty Guidelines in effect at the time of eligibility determination. HRSA sought and received public comment on this planned revision to the Eligibility Guidelines through a separately published **Federal Register** notice. Therefore, this final rule does not address that aspect of the Executive Order.

*C. Advisory Committee on Organ Transplantation Recommendations*

In May 2019, the HHS Advisory Committee on Organ Transplantation (ACOT) voted to provide recommendations to the Secretary which, if adopted, would increase access to organs from living organ donors by providing living organ donors with additional support and resources and by removing disincentives that may have prevented them from donating. This final rule is responsive to those recommendations.

*D. Section 301 of NOTA*

Section 301 of NOTA generally 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.'' [6] Therefore, reimbursement payments received via HRSA's reimbursement program must not violate section 301 of NOTA, which 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 state whether reimbursement for 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 is not valuable consideration under section 301 of NOTA. Therefore, this prohibition does not pose a barrier to the Secretary's determination, made through this final rule, that the reimbursement of such expenses is appropriate under the authority provided by 42 U.S.C. 274f(a)(2).

## III. Summary of This Rule

This rule codifies the proposed amendments to the OPTN Final Rule described in the December 2019 NPRM and removes barriers and disincentives to living organ donation by adding lost wages, and child-care and elder-care expenses incurred by caregivers, as reimbursable expenses for living organ donors. This rule constitutes the Secretary's determination by regulation that reimbursement may be appropriately provided for lost wages, and child-care and elder-care expenses incurred by caregivers who make living donations of their organs, as authorized by section 377(a)(2) of the PHS Act. A new regulatory section is added 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 organ donors and other individuals evaluated for living organ donation for lost wages and child-care and elder-care expenses incurred by caregivers while making donations of their organs. Concurrently with the publication of this final rule, HRSA will revise the Eligibility Guidelines to address eligibility criteria for these reimbursable expenses.

*A. Lost Wages*

Some potential living organ donors may be willing and available to donate an organ to a family member, friend, or an unknown recipient, but might 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. Through this final rule, HRSA determines that lost wages are an appropriate reimbursable expense for living organ donors, and adds 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. Through this final rule, HRSA determines that child-care and elder-care expenses incurred by caregivers are appropriate reimbursable expenses for living organ donors, and adds child-care expenses at § 121.14(a)(2) and elder-care expenses at § 121.14(a)(3) as categories of reimbursable non-medical incidental expenditures.

## IV. Public Comments and Responses

HRSA received a total of 267 comments from the public, including professional and patient stakeholder organizations, prior and potential living

[6] *See* 42 U.S.C. 274e(a).

kidney donors, donor stakeholder organizations, and clinical professionals. The vast majority (261) of commenters were in favor of the proposed rule, although several suggested modifications to the proposed rule (see details below). Only two commenters opposed the spirit of the proposed rule and expressed concern about the well-being of living organ donors.

All comments were considered in developing this rule. This section presents a summary of all major issues raised by commenters, grouped by subject, as well as responses to the comments.

*1. Additional Financial Barriers to Organ Donation/Foregone Medical Insurance Benefits*

HRSA specifically sought public comment on any literature or evidence on additional financial barriers to living organ donation, including whether foregone medical insurance benefits pose a significant barrier to living organ donation. In the NPRM, HRSA noted an interest in public comment regarding whether such expenses should be included in future rulemaking. Only three commenters from professional societies explicitly addressed HRSA's request for comments on whether ''foregone medical insurance benefits'' pose a significant barrier to living organ donation. These commenters did not provide literature or evidence in support of this additional category, but suggested it was appropriate for reimbursement to address concerns regarding potential impacts due to time away from work after donation.

*Response:* HRSA appreciates the feedback on the inclusion of ''foregone medical insurance benefits'' as a potential category of expenses eligible for reimbursement. HRSA reiterates its interest in receiving any detailed literature or evidence regarding how these expenses pose a barrier to living organ donation.

*2. Definition of Lost Wages*

We received five comments suggesting that HRSA include lost income as a reimbursable non-medical expense rather than ''lost wages.'' The commenters argue that lost income would more accurately reflect the potential disincentives to living organ donation. Specifically, the commenters suggest that lost wages may not include income received by independent contractors or others who do not receive a standard hourly, weekly, or monthly wage. The commenters further suggest that ''lost income'' would include foregone sick days, vacation pay, or disability payments that would otherwise have been available to the living organ donor.

*Response:* HRSA intends to proceed with the use of the term ''lost wages'' when describing available reimbursable incidental non-medical expense. The term ''lost wages''' is consistent with the direction to HHS provided in the July 2019 ''Advancing American Kidney Health'' E.O., and reflects the terminology used in the categories of expenses excluded from valuable consideration as defined in section 301 of NOTA.

HRSA does wish to make clear that ''lost wages'' need not be limited to consideration of traditional wage rate income. HRSA agrees that living organ donors with non-traditional or irregular income should be eligible for reimbursement of lost wages through the program if sufficient documentation of the lost wages is provided. The program will provide eligible donors with informational packets containing documentation requirements for reimbursement of lost wages through participating transplant programs; information will also be posted on the program's website. Regarding the inclusion of reimbursement for foregone sick days, vacation pay, or disability payments, HRSA is not including these categories as reimbursable incidental non-medical expenses at this time. More analysis is needed to determine whether including such expenses would be consistent with the statutory requirement that HRSA's reimbursement program cannot cover donor expenses that can be reimbursed from certain other sources, as detailed in 42 U.S.C. 274f(d).

3. Additional Incidental Non-Medical Expenses

We received two comments suggesting that pet care expenses also be included as reimbursable incidental non-medical expenses, given that a large proportion of potential donors are also pet owners who may incur expenses for pet care during their recovery after organ donation.

*Response:* HRSA appreciates the feedback on the inclusion of pet care as a reimbursable incidental non-medical expense. HRSA is not aware of literature or evidence regarding the impact pet care expenses may have as a disincentive to living organ donation. Therefore, HRSA is not including pet care as a reimbursable expense at this time. However, HRSA is interested in any evidence regarding the impact of pet care expenses posing a barrier to living organ donation.

*4. Other Comments*

a. Insurance Access

Eight commenters suggested that HHS take action to address the potential that living organ donors may be adversely impacted in access to health or life insurance, post-donation. The commenters cite experience and literature describing increased insurance premiums and a higher likelihood of denial of coverage for living organ donors. Several commenters raised the issue of medical problems that might arise post-donation and whether those expenses would be covered by health insurance. One commenter described the experience of a family member who had subsequent difficulty getting health insurance coverage, despite being in good health. Another individual stated that he was so concerned about his insurance company canceling his coverage that he never informed his insurance company that he had donated an organ. One commenter asked that HRSA consider the limited coverage that the average health insurance plan provides to living organ donors, and expressed concern that living organ donors who experience complications related to the donation may be personally responsible for the medical costs.

*Response:* HRSA acknowledges and appreciates commenters sharing these concerns. The purpose of HRSA's reimbursement program is to provide living organ donors with support by reimbursing non-medical expenses that pose a disincentive to living organ donation. HRSA will continue to analyze these issues.

b. Other Uncovered Medical Expenses

Approximately 14 commenters suggested that HRSA's reimbursement program be expanded to cover medical expenses related to the living organ donation that are not otherwise covered by their or the recipient's health insurance.

*Response:* The purpose of HRSA's reimbursement program is to provide living organ donors with support by reimbursing non-medical expenses that pose a disincentive to living organ donation. The statute authorizing HRSA's reimbursement program, section 377 of the Public Health Service Act, does not provide authority for the program to reimburse living organ donors for medical expenses related to living organ donation. Therefore, it is beyond the purview of the program to cover additional medical expenses or serve as a form of supplemental health insurance for living organ donors.

b. Payer of Last Resort

Approximately four commenters expressed concern about the description of HRSA's reimbursement program as a payer of last resort. The commenters suggest that this description may go beyond the requirements of section 377 of the Public Health Service Act, that requires that the program not cover expenses ''of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, concerning such expenses (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; (2) by an entity that provides health services on a prepaid basis; or (3) by the recipient of the organ.'' The commenters also suggest that the complexity of this structure unduly burdens the living organ donor by requiring documentation that the expenses are not otherwise covered, which could be a disincentive to living organ donation. Another commenter stated that this description is too narrow, and inconsistent with the benefits of reimbursing living organ donors. And finally, one commenter believed that the phrase implies that the program's reimbursement should be as limited as possible and could be considered to indicate that transplant recipients should be required to reimburse their donors as a matter of course.

*Response:* HRSA accepts these comments, and will no longer use the phrase ''payer of last resort'' to explain HRSA's reimbursement program. HRSA did not intend to imply any limitation of reimbursable expenses beyond the statutory requirements. However; per statute, HRSA's reimbursement program cannot cover donor expenses that can be reimbursed from certain other sources, as detailed in 42 U.S.C. 274f(d)—(1) any State compensation program, an insurance policy, or a Federal or State health benefits program; (2) an entity that provides health services on a prepaid basis; or (3) the recipient of the organ. Regarding the concern about how living organ donors might need to document that their potentially reimbursable expenses are not covered by other programs or individuals, HRSA maintains that sufficient documentation will be required to assure that its reimbursement program is operating within the authority of section 377 of the Public Health Service Act.

c. Compensation for Intangible Risks

Approximately eight commenters suggested that the program also address compensation for intangible risks incurred by living organ donors, including the surgical risks of donation, the long-term risks to donor health, the inconvenience and discomfort of surgery, and the concern that a friend or relative may need a kidney in the future.

*Response:* As previously discussed, HRSA's reimbursement program is limited by statute and may not provide compensation to living organ donors beyond reimbursement for eligible expenses. Undertaking a ''risk,'' whether it be a long-term health risk or surgical risk, is not an eligible expense.

d. Donor Caretaker

Six commenters suggested that HRSA's reimbursement program expand coverage to allow for reimbursement of expenses incurred by a ''donor caretaker'' who provides care for the living organ donor during post-operative recovery. The commenters stated that, since living donors rely on caretakers as they recover from surgery, these caretakers should be compensated for lost income. In addition, they argued that potential financial burdens that might be incurred by the donor's caretaker(s) constitute a disincentive for living organ donation. As such, they believe that removing this disincentive by covering ''donor caretaker'' expenses would increase living organ donation rates.

*Response:* Individuals eligible for reimbursement of expenses under HRSA's reimbursement program are limited to those who meet the statutory definition of ''donating individual'' and those referenced in the statutory definition of ''qualifying expenses'' for the program.[7] This statutory language limits reimbursement for expenses incurred by actual living organ donors, or ''individuals who in good faith incur qualifying expenses toward the intended donation of an organ,'' to allow for expenses incurred by potential donors who are ruled out for organ donation. The statute also allows for reimbursement for qualifying expenses incurred by up to two individuals who ''accompany or assist the donating individual'' for the purposes of living organ donation.

To date, HRSA has allowed for the reimbursement of travel and subsistence expenses related to the donation procedure for up to two ''donor caretakers'' providing assistance to the donating individual, whether the expenses were incurred before or after the donation procedure. This final rule allows that the additional expenses of lost wages, child-care, and elder-care are eligible for reimbursement, whether incurred by the donor or by the up to two accompanying or assisting individuals. Reimbursement of these expenses for accompanying or assisting individuals will be subject to availability of funds and as provided in the program's Eligibility Guidelines.

f. Change in Eligibility Criteria and ''Primary Caregiver''

HRSA received 31 comments encouraging a change in the program's eligibility criteria, including raising the threshold income level. A subset of those comments also questioned the references to ''primary caregiver'' in the NPRM preamble, and recommended removing the ''primary'' qualifier. The commenters expressed concern that the references to ''primary caregiver'' appeared to limit the number of individuals eligible for reimbursement for child-care and elder-care expenses. For example, one commenter expressed concern that it will be difficult to determine the ''primary caregiver'' and that all donors with caretaker responsibilities for children or elders should receive reimbursement if they need to pay someone else to take on those responsibilities during their recovery.

*Response:* With regard to a change in the current program eligibility criteria, note that, as previously stated, HRSA will revise the current Eligibility Guidelines, including consideration of an increase to the upper threshold for living organ donor and organ recipient household income. HRSA intends to publish a **Federal Register** notice during fiscal year 2020 regarding this issue.

With regard to the preamble's references to ''primary caregiver,'' HRSA recognizes there may have been some confusion with regard to this term. HRSA intends that all donors and potential donors with caregiver responsibilities for children or elders should be eligible for reimbursement for child-care or elder-care expenses. HRSA originally included this qualifier not to limit eligibility, but rather to indicate that any caregiver, despite their familial relationship, may be eligible for reimbursement under the program. Based on an analysis of the feedback, HRSA no longer uses the qualifier ''primary'' for ''caregiver'' in the preamble language in this final rule. HRSA intends to further address which individuals are eligible caregivers in the program's Eligibility Guidelines.

g. Safety of Living Organ Donation

Two commenters expressed complete opposition to the rule based on concern about the overall safety of living organ donation and well-being of living organ donors. These commenters expressed

[7] *See* 42 U.S.C. 274f(c).

specific concern regarding the potential risk to the living organ donor's health, the invasiveness of the procedure, and the cost of the surgery.

*Response:* HRSA recognizes that living organ donation is not without risk. We note in the preamble that the benefits of living organ donation must be weighed against risks to the donor. For anyone considering living organ donation, it is critical to gather as much information as possible to make an informed decision. Potential living organ donors should also ensure that they undergo a thorough screening prior to donation and receive counseling regarding informed consent.[8] Access to follow-up care and maintenance of a healthy lifestyle post-donation are also beneficial to the short- and long-term health of the living donor.[9] HRSA emphasizes that the decision to become a living organ donor is an individual choice. The purpose of this rule is to expand the scope of financial support available to those who decide to become living organ donors, in the form of reimbursement for qualifying expenses.

h. Impact of Rule Change on Other Existing Program

Four commenters (two public and two professional stakeholder organizations) expressed support for the concept of supporting living organ donors but opposition to the proposed rule. These commenters, including a non-profit organization that operates a national registry in the United States that lists kidney donors and recipients in need of a kidney transplant, argue that the proposal does not go far enough in providing reimbursement for living organ donors and would supplant an existing program established and operated by this organization that provides a broader array of support. The range of support from the referenced program includes reimbursement for lost wages, as well as ''donation life insurance,'' ''donation disability insurance,'' and legal support, should it be necessary.

These four comments suggest restructuring HHS' approach to addressing living organ donor expenses to allow for a public-private collaboration between HHS and this organization.

*Response:* HRSA appreciates the feedback and will continue to consider innovative models for future actions to support living organ donors. Nevertheless, HRSA is proceeding with finalizing the proposal outlined in the NPRM through this final rule. HRSA wishes to note that other entities, including the non-profit organization referenced above, are eligible to compete for future cooperative agreements for the operation of the living organ donor reimbursement program. Those entities are encouraged to submit proposals.

i. Miscellaneous

Other commenters raised a variety of issues that do not pertain directly to the expansion of reimbursable incidental non-medical expenses under the program, which was the focus of the proposed rule. HRSA will continue to analyze these issues.

- Allowing non-directed donors to receive reimbursement through the program which is currently tied to recipient income levels.
- Removing donor residence requirement to allow non-U.S. residents/citizens to participate in the program.

## V. Statutory and Regulatory Requirements

*Executive Orders 12866, 13563, and 13771: Regulatory Planning and Review*

HHS examined the effects of this rule as required by E.O. 12866 on Regulatory Planning and Review, E.O. 13563 on Improving Regulation and Regulatory Review, the Regulatory Flexibility Act (Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), E.O. 13132 on Federalism, and E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs.

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 outlined 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 rule has been determined to be a significant regulatory action. Accordingly, the 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.'' This rule is neither regulatory nor deregulatory for purposes of E.O. 13771. There are no additional costs; as finalized, this rule 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. As described in more detail in the following paragraph, 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. Secondly, donor income also appears to play a role in living organ donor transplant rates.

Research showed the implementation of new laws, including a move toward reimbursing lost wages and providing other benefits, yielded the country of Israel a 65 percent increase in kidney transplants from living donors.[10] In the United States, paying donation-related

[8] See *Ann Intern Med.* 2018;168:276–284. doi:10.7326/M17–1235.

[9] See *Kidney Disease: Improving Global Outcomes* (KDIGO) Living Kidney Donor Work Group. KDIGO Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors. *Transplantation* 2017; 101(Suppl 8S):S1–S109.

[10] 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.

travel costs through NLDAC increased the number of living donor kidney transplants by approximately 14 percent over baseline in participating transplant centers,[11] with a separate survey of NLDAC donors revealing that 75 percent of donors would not have donated without reimbursement.[12] In addition, tax incentive legislation in New York increased living kidney donations to non-family members by 52 percent.[13] 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.[14]

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 financial incentives involves the interplay of several 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. titled ''Advancing American Kidney Health'' also directed HHS to propose raising the limit on the income of living organ 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.

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 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 (*e.g.,* 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 workweek, 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 [15] 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 [16] child-care will cost $1,680–$2,520 over 4–6 weeks.
- *Elder-care:* At $504 per full week [17] 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 reimbursement 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. Approximately nine (9) percent of participants exceeded a reimbursement of $5,500 or more. HRSA may adjust the cap to account for the additions of 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 [18] estimated End-Stage Renal Disease (ESRD) expenditures to be $292,117 over ten years per beneficiary on dialysis. Living donor kidney transplants (LDKT) was cost-saving at ten 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 ten years for LDKT compared to maintenance dialysis is likely a lower bound, since living donation is likely to 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 ten 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

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

[12] 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.

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

[14] 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.

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

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

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

[18] 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.*

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. Still, 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 ten years relative to the baseline spending projection of $292,117 over ten 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 after 30 months of coordinated medical services; it takes 30 months for Medicare to become the primary payer for diagnosed end stage renal disease patients, 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 ten 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.[19]

A. 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 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 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 was $154 million. HHS does not expect this rule to exceed the threshold.

C. Executive Order 13132—Federalism

HHS has reviewed this rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have ''federalism implications.'' This rule would not ''have substantial direct effects on the States, or 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 rule is projected to have no impact on current reporting and recordkeeping burden, as the amendments outlined in this rule will not impose any data collection requirements under the PRA.

**List of Subjects in 42 CFR Part 121**

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

Dated: September 15, 2020.

**Thomas J. Engels,**

*Administrator, Health Resources and Services Administration.*

Approved: September 16, 2020.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

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

## PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

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

■ 2. 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 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.

[19] Obtained from proposed rule CMS–5527–P S*pecialty 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.*

(b) [Reserved]

[FR Doc. 2020–20804 Filed 9–18–20; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 635

**[Docket No. 180117042–8884–02; RTID 0648–XA483]**

### Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; quota transfer.

**SUMMARY:** NMFS is transferring 111.6 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the General category. This action is intended to account for an accrued overharvest of 63.3 mt from previous time period subquotas, and to provide further opportunities for General category fishermen to participate in the September General category fishery, based on consideration of the regulatory determination criteria regarding inseason adjustments. This action would affect Atlantic tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

**DATES:** Effective September 17, 2020 through September 30, 2020.

**FOR FURTHER INFORMATION CONTACT:** Sarah McLaughlin or Nicholas Velseboer, 978–281–9260, or Larry Redd, 301–427–8503.

**SUPPLEMENTARY INFORMATION:** Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

The current baseline General and Reserve category quotas are 555.7 mt and 29.5 mt, respectively. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a ''subquota'' or portion of the annual General category quota. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward from one time period to the next and is available for use in subsequent time periods. At the time of drafting this notice, NMFS has taken four actions that resulted in adjustments to the General and Reserve category quotas, resulting in currently adjusted quotas of 113 mt of quota for the Reserve category, 100 mt for the General category January through March 2020 subquota period, and 9.4 mt for the December 2020 subquota period (85 FR 17, January 2, 2020; 85 FR 6828, February 6, 2020; 85 FR 43148, July 16, 2020).

**Transfer of 111.6 mt From the Reserve Category to the General Category**

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories, after considering regulatory determination criteria provided under § 635.27(a)(8). NMFS has considered all of the relevant determination criteria and their applicability to this inseason quota transfer. These considerations include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by General category fishermen and provided by tuna dealers provides NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT in the General category would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the General category quota to date (including during the summer/fall and winter fisheries in the last several years), and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). Preliminary landings data as of September 15, 2020, indicate that the General category landed a cumulative total of 441.2 mt through August 31, which exceeds the cumulative adjusted quota available through August 31, *i.e.,* 377.9 mt. Preliminary September landings as of September 15, 2020, are 114.2 mt, which represents 78 percent of the baseline September subquota (147.3 mt). At the time of drafting of this inseason action, the General category subquota has not yet been exceeded, but without a quota transfer at this time, NMFS would likely close the General category fishery shortly, and participants would have to stop bluefin tuna fishing activities while commercial-sized bluefin tuna remain available in the areas where General category permitted vessels operate at this time of year. Transferring 111.6 mt of quota from the Reserve category would account for 63.3 mt of accrued overharvest from the prior time periods and result in an additional 48.3 mt being available for the September 2020 subquota period after, thus effectively providing limited additional opportunities to harvest the U.S. bluefin tuna quota while avoiding exceeding it.

Regarding the projected ability of the vessels fishing under the particular category quota (here, the General category) to harvest the additional amount of BFT quota transferred before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS considered General category landings over the last several years and landings to date this year. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors, such as the restrictions that some dealers placed on their purchases of BFT from General category participants this year. A portion of the transferred quota covers the 63.3-mt overharvest in the category to date, and NMFS anticipates that General category participants will be able to harvest the remaining 48.3 mt of transferred BFT quota by the end of the subquota time period. In the unlikely event that any of this quota is unused by September 30, such quota will roll forward to the next subperiod within the calendar year (*i.e.,* to the October through November period), and NMFS anticipates that it would be used before the end of the fishing year. NMFS also anticipates that some underharvest of the 2019 adjusted U.S. BFT quota will be carried forward