

On December 17, 2019, Health Resources and Services Administration (HRSA) announced a Notice of Proposed Rulemaking (NPRM) which proposes to expand the scope of reimbursable expenses incurred by living organ donors to include lost wages and child-care and elder-care expenses. This proposal, once finalized, would remove potential barriers to living organ donations.

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. This NPRM aligns with the Executive Order, which also included language to specifically allow for the reimbursement of lost wages along with child-care and elder-care expenses. HRSA is separately preparing a notice that will increase the income threshold for living donors eligible for reimbursements.

Current statutory language permits reimbursement for the "incidental non-medical expenses" of donors but only after the Secretary determines by regulation that the reimbursement of such expenses is appropriate. This NPRM is the first time the Secretary is proposing to determine that certain categories of "incidental non-medical expenses" incurred toward living organ donation are appropriate for reimbursement. In proposing to amend the OPTN Final Rule to permit these expenses as "incidental non-medical expenses," HHS has clarified that reimbursement for such expenses is not "valuable consideration" for purposes of section 301 of NOTA, and thus such payments do not violate the criminal prohibition against the exchange of valuable consideration for organs for use in transplantation.

Comments on the proposed rule are due 60 days after publication in the Federal Register.

## **BACKGROUND**

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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. To date, approximately 96,000 individuals are on the national waiting list awaiting an available kidney. 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 help reduce these numbers. 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.

Federal law (42 U.S.C § 274f) allows the Secretary to reimburse for travel and subsistence expenses incurred toward living organ donation. In 2006, under this authority, HRSA established a "Reimbursement of Travel and Subsistence Expenses toward Living Donation" program (Program), which is currently operated as the National Living Donor Assistance Center. HRSA's reimbursement program specifically aims to assist donors who lack other forms of financial support. The Program currently provides for reimbursement of up to \$6,000 in expenses, including travel, lodging, meals, and incidental expenditures related to donor evaluation or other donation related medical procedures.

Under Federal law, the National Living Donor Assistance Center (NLDAC), which provides reimbursements to living organ donors through a federally funded grant, 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. 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.

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. 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, or the loss of medical insurance benefits, 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 care-givers 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.

Living organ donation provides a number of 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 improved survival rates for organ recipients. 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.

Several government agencies, including the Centers for Medicare & Medicaid Services (CMS), regulate different aspects of the U.S. organ transplant system. CMS has also issued a proposed rule that would update the Organ Procurement Organization (OPO) Conditions for Coverage that OPOs must meet to receive Medicare and Medicaid payment.

As a key goal, the President's Executive Order and this proposed rule seek to help the almost 113,000 people in the United State currently on the waiting list for a lifesaving organ transplant, which far exceeds the number of transplantable organs. HHS and HRSA are committed to reducing the number of individuals on the organ transplant waiting list by increasing the number of organs available for transplant.

For more information on today's announcement, read the [HHS press release](#).