



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation

Program Eligibility Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice; request for public comment.

SUMMARY: HRSA published the final eligibility guidelines for the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program (herein referred to as Program) in the **Federal Register** on October 5, 2007. HRSA is requesting public comment concerning proposed changes to the guidelines to: increase the household income eligibility threshold to 350% (currently, the threshold is 300%) for living organ donors and organ recipients, clarify the use of the existing preference categories in relation to the proposed household income eligibility threshold, and clarify that travel and subsistence expenses incurred by non-directed living organ donors qualify as reimbursable expenses under the Program. HRSA is also proposing to revise the Program eligibility guideline's background section to ensure that the information aligns with the Program's legislative authority. These proposed guidelines would apply to the Program regardless of the awardee of the cooperative agreement that administers the Program.

DATES: Written comments must be submitted to the office in the address section below by mail or e-mail on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Please send all written comments to Frank Holloman, Director, Division of Transplantation, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W53A, Rockville, Maryland 20857; telephone (301) 443-7577; or e-mail: donation@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Frank Holloman, Director, Division of Transplantation, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W53A, Rockville, Maryland 20857; telephone (301) 443-7577; or e-mail donation@hrsa.gov.

SUPPLEMENTARY INFORMATION: The purpose of the Program is to reimburse travel and subsistence expenses and other incidental non-medical expenses that the Secretary of HHS may authorize by regulation to living organ donors and up to two relatives or other individuals accompanying the living donor in the United States. Under the statutory authority for the Program, if an organ recipient can reasonably be expected to pay the living organ donor's travel and subsistence expenses related to the organ donation, reimbursement of such expenses through the Program is prohibited. The current eligibility guidelines further clarify that to be eligible for donor reimbursement, the organ recipient's household income must not exceed 300 percent of the HHS Poverty Guidelines in effect at the time of the eligibility determination. Alternatively, if the organ recipient's household income exceeds the threshold, he/she can be eligible to participate in the Program if the individual can demonstrate financial hardship. In addition, the Program uses a household income threshold of 300 percent of the HHS Poverty Guidelines in effect at the time of the eligibility determination to prioritize reimbursement for prospective living organ donors based on an assessment that donors whose income is below that threshold are less likely to be able to cover qualified expenses under the Program.

At the inception of the Program in 2007, HRSA proposed a household income eligibility threshold of 200 percent of the HHS Poverty Guidelines; however, after reviewing and considering the public comments received, HRSA set the Program's initial threshold at 300 percent of household income. HRSA further determined, based on public comment, that organ recipients whose income exceeded this level were reasonably able to reimburse living organ donors for travel and subsistence expenses as well as for other qualifying expenses authorized by the Secretary of HHS, unless the recipients demonstrated financial hardship. HRSA also established that donors whose incomes fell below this threshold should receive preference over donors whose incomes exceeded this threshold.

The Program's eligibility guidelines have not been amended since 2009. With the annual number of waiting list deaths hovering between 6,000 and 7,000 since 2001, the transplant community continues to look to living organ donation as a life-saving option for patients in need of organ transplants, particularly kidney and liver transplants. As of December 31, 2019, approximately 84 percent of the nearly 113,000 individuals on the national transplant waiting list were waiting for a kidney transplant. Even with a record number of close to 40,000 organ transplants performed in the United States in 2019, including almost 7,400 living donor transplants, the gap between demand and availability of organs persists.

In May 2019, the Advisory Committee on Organ Transplantation (ACOT) made several recommendations regarding support to living organ donors. ACOT advises and provides recommendations to the Secretary through the HRSA Administrator on all aspects of organ donation, procurement, allocation, and transplantation. ACOT offered three recommendations aimed at amending the Program's eligibility guidelines to allow for

increased access. ACOT recommended increasing the household income eligibility threshold to 500 percent of the Federal Poverty Limit, waiving income verification when reimbursements do not exceed \$500, and making non-directed donors eligible for reimbursement through the Program if other program requirements are satisfied.

The Executive Order on Advancing American Kidney Health, issued on July 10, 2019, provides increased support for living donors with the goal of increasing the supply of transplantable kidneys (<https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>). Section 8 of the Executive Order requires the Secretary of HHS to, in part, “...raise the limit on the income of donors eligible for reimbursement under the [P]rogram.”

In addition to proposing an increase in income eligibility for the reimbursement program through this notice, on December 20, 2019, HRSA published a notice of proposed rulemaking designed to further reduce financial barriers to living organ donation by expanding the list of reimbursable costs to include lost wages and child-care and elder-care expenses (84 FR 70139).

In furtherance of the Executive Order and in light of the ACOT recommendations, as well as budgetary constraints, HRSA proposes amending the Program eligibility guidelines as follows:

1. increasing the household income eligibility threshold for organ recipients and prospective living organ donors from the current 300 percent of the HHS Poverty Guidelines to 350 percent of the HHS Poverty Guidelines in effect at the time of eligibility determination;

2. clarifying the use of the existing preference categories in relation to the proposed income eligibility threshold; and
3. amending the qualifying expenses section of the eligibility guidelines to allow the Program to reimburse eligible non-directed donors for qualifying expenses.

Under the first proposed change, the revised income eligibility threshold will cover applicants living in nearly 70 percent of the households in the United States and potentially increase an important source of life-saving organ transplants for the men, women, and children on the national transplant waiting list by reducing financial barriers to living organ donation. As this proposal would increase the income eligibility threshold for organ recipients, and given that reimbursement under the Program is not permitted if Program expenses can reasonably be expected to be covered by organ recipients, HRSA is specifically seeking input from the public regarding whether an organ recipient's reasonable ability to pay for a donor's expenses should remain tied to the Program's income eligibility threshold and whether or not the proposed threshold is appropriate and/or justified. In 2019, the HHS Poverty Guideline for a family of four was \$25,750.

The second proposal is to clarify how the Program will use the existing preference categories in relation to the proposed income eligibility threshold. The Program is currently stratified into 4 preference categories, which play a role in prioritizing applicants: (1) both donor's and recipient's incomes are below the threshold; (2) recipient's income is below the threshold but donor demonstrates financial hardship; (3) recipient's income is below the threshold regardless of donor's income; and (4) recipient's income is above the threshold but demonstrates financial hardship regardless of the donor's income. Under this proposal, the Program will accept applications primarily from preference category 1, both donor and

recipient household incomes at or below 350 percent of the HHS Poverty Guidelines. However, the Program may accept applications from each subsequent category as funds become available. The Program will inform participating transplant programs directly and the public via the Program's website whenever it plans to accept or stop accepting applications from the other preference categories.

This proposed change will help ensure that HRSA, through this Program, supports individuals in need of life-saving transplants who are unable to pay for their living donors' travel and related expenses, as required by the Program's authorizing legislation. In addition, the proposed change will enable living organ donors who are unable to afford these expenses to receive preference, as required by the Program's authorizing legislation. HRSA is proposing this change to ensure that the Program meets its statutory requirement to support donor and recipient pairs with the greatest financial needs. The Program will regularly track percentages of funds spent against percentages of the funds remaining for the budget year.

The third proposed change is to amend the qualifying expenses section of the eligibility guidelines to allow the Program to reimburse eligible non-directed donors for qualifying expenses when the intended transplant recipient cannot be identified prior to the donation process. Living organ donations can be either "directed" (the organ is intended for an individual named or specified by the living organ donor), or "non-directed" (the organ is intended for an individual neither named nor specified by the donor) as defined at <https://optn.transplant.hrsa.gov/resources/ethics/living-non-directed-organ-donation/>. Currently, a non-directed living organ donor can only be reimbursed for qualified expenses if the intended recipient is identified prior to the donation process and the intended recipient meets the Program eligibility requirements, including family household income. Under the

proposed change, all non-directed donors will be eligible for reimbursement for qualified expenses. This proposed change will allow the Program to support non-directed donors without considering the income eligibility of intended transplant recipients, if all other donor eligibility criteria are met. Removing this financial barrier is expected to increase the number of non-directed donors, who often donate anonymously with altruistic motives. In addition, because non-directed donors serve as catalysts for paired donation kidney chains, this proposed change would provide increased access to life-saving organ transplants to more patients on the waiting list.

Additionally, HRSA is proposing to revise the Program eligibility guidelines' background section to ensure that the information aligns with the Program's legislative authority. The background section includes information about the current awardee of the cooperative agreement and the mechanism used by the awardee to administer this national program. This proposed change will ensure that the background covers only the legislative requirements for this Program without focusing on the award recipient. This will eliminate the need to revise the Program eligibility guidelines in the event of a change to the awardee of the cooperative agreement.

These proposed changes to the eligibility guidelines, if implemented, would provide increased access to life-saving organ transplants to the thousands of men, women, and children on the national transplant waiting list by reducing financial barriers for the individuals who wish to become living organ donors. These proposed changes are in accordance with the legislative authority codified at section 377 of the Public Health Service Act, 42 U.S.C. 274f, and the Executive Order on Advancing American Kidney Health issued on July 10, 2019.

Thomas J. Engels,

Administrator.

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