



Billing Code 4165-15

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: Final notice; response to solicitation of comments and publication of final program eligibility guidelines

SUMMARY: A notice was published in the Federal Register on March 31, 2020, to solicit comments on the eligibility criteria that were proposed by HRSA concerning the Living Organ Donation Reimbursement Program (formerly Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program). This final notice responds to comments, describes the revision to the eligibility criteria to incorporate the reimbursable categories of qualifying expenses added by an HHS final rule published elsewhere in the issue of the Federal Register, and finalizes the Program Eligibility Guidelines.

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 email donation@hrsa.gov.

SUPPLEMENTARY INFORMATION: Congress has provided specific authority under section 377 of the Public Health Service (PHS) Act, as amended, 42 U.S.C. 274f, for providing reimbursement of qualifying expenses incurred toward living organ donation with preference for those for whom paying such expenses would create a financial hardship. In August 2019, HRSA awarded a 5-year, \$16,250,000 cooperative agreement to the University of Kansas Medical Center Research Institute, Inc. to administer this Program.

Congress requires that the Secretary in carrying out this Program give preference to those individuals the Secretary determines are more likely to be unable to pay for the qualifying expenses associated with the donation process. In addition, Congress requires that funds from the Program not be used to reimburse qualifying expenses associated with being a living organ donor, if the donor has received any payments or is expected to receive any payments related to these expenses from:

- (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.

In addition, the authorizing statute requires the Secretary to give preference to living organ donors who are “more likely to be otherwise unable to meet such expenses.”

Summary of Comments and HRSA Responses

On March 31, 2020 (85 FR 17894), HRSA published a notice in the Federal Register requesting comments on the proposed eligibility criteria for the Program. HRSA requested

public comment concerning proposed changes to the guidelines to: increase the household income eligibility threshold to 350 percent of the HHS Poverty Guidelines (from the current threshold of 300 percent) 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 donors¹ qualify as reimbursable expenses under the Program. HRSA also proposed revision of the Program eligibility guidelines' 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 recipient of the cooperative agreement that administers the Program.

HRSA received a total of seventy-seven comments from the public. Comments were received from individuals, including prior living donors, and professional and patient stakeholder organizations. None of the commenters opposed HRSA's efforts to expand eligibility under the Program, although two commenters expressed concern about the effectiveness of the Program, and most commenters expressed interest in further expanding the program. Sixty-eight of the commenters proposed that HRSA increase the income eligibility threshold for the recipient and the donor of the organ beyond the proposed 350 percent of the HHS Poverty Guidelines. HRSA assumes that recipients whose income exceeds this level will have the ability to reimburse the living organ donor for the qualified expenses incurred toward living organ donation. HRSA also assumes that donors whose income is below this threshold are "more likely to be otherwise unable to meet such

¹ 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/>.

expenses.” Fifty-one of these commenters specified that the threshold should be at least 500 percent of the HHS Poverty Guidelines. Forty-four commenters suggested that eligibility should not be linked to the recipient’s income. Four commenters remarked that reimbursement should be available to all living organ donors without conditions. Finally, three commenters expressed concern that the eligibility criteria do not adequately consider the financial burdens that may occur when both the living organ donor and the transplant recipient reside in the same household.

HRSA wishes to thank the respondents for the quality and thoroughness of their comments. HRSA’s response to the comments received and final decisions are discussed below.

I. Response to Comment to Increase the Income Threshold to 500 percent of the HHS Poverty Guidelines

Sixty-eight of the commenters proposed that HRSA increase the threshold beyond the proposed 350 percent of the HHS Poverty Guidelines, with many of these commenters specifying that the threshold should be at least 500 percent of the HHS Poverty Guidelines consistent with a recommendation of the HHS Advisory Committee on Organ Transplantation.

HRSA notes that the authorizing statute requires the Program to give preference to individuals who are “more likely to be otherwise unable to meet such expenses.” The authorizing statute also requires that the Program not provide reimbursement for donor expenses that have been paid, or can reasonably be expected to be paid by other existing programs or by the recipient of the organ. Based on these requirements, and in an effort to provide for a transparent and administratively manageable mechanism to assess an

individual's ability to pay for covered expenses, HRSA believes that an income threshold based on the recipient's income in relation to the HHS Poverty Guidelines provides a reasonable mechanism for evaluating this standard. HRSA also notes the importance of maintaining a mechanism for applicants to the Program to demonstrate financial hardship not adequately reflected by the recipient's income, which would indicate undue hardship if the recipient were to reimburse the donor's expenses.

HRSA will closely monitor the Program's ability to adequately address the reimbursement needs of applicants meeting any of the four preference categories based on the 350 percent income threshold defined in the eligibility criteria, including those applicants who meet the financial hardship criteria. This is especially important to monitor in relation to HRSA's recent regulatory action permitting reimbursement of lost wages and child-care and elder-care expenses through the Program. This expansion of eligible expenses is expected to further remove financial disincentives to living organ donation and expand participation in the Program. However, the full impact of the expansion of eligible expenses and the increased income eligibility threshold on participation in the Program is not yet fully known. HRSA will monitor and analyze the impact of this change to inform future program operations

II. Response to Comment that Recipient Income Should Not Be Considered in Determining Eligibility

Forty-four commenters suggested that eligibility should not be linked to the recipient's income. As stated previously, the authorizing statute requires that HRSA consider the recipient's ability to reimburse the donor's expenses and prohibits the Program from reimbursing expenses that can reasonably be expected to be covered by the transplant

recipient. HRSA specifically sought 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. Some respondents suggested that the Program require a certification from donors that they do not expect to be reimbursed by the recipient. Similarly, some commenters suggested that such a certification and means testing are not necessary because in practice donors' expenses are not being regularly reimbursed by recipients. However, these suggestions do not meet the statutory requirement that HRSA prohibit payment for expenses that "can reasonably be expected to be made" by the recipient of the organ. HRSA acknowledges that recipient income is not a full measure of whether recipients can reasonably be expected to reimburse their donor for qualified expenses. However, HRSA is prohibited by statute from reimbursing donor expenses that can reasonably be expected to be reimbursed by the recipient of the organ. Therefore, HRSA expects the recipient of the cooperative agreement to provide education and clarity on the process for demonstrating financial hardship. HRSA acknowledges that determining recipients' financial hardship may be administratively burdensome and is committed to working with the recipient of the cooperative agreement to develop procedures to minimize burden while meeting the statutory requirements. Therefore, HRSA has decided to maintain consideration of recipient income in the preference categories at this time.

III. Response to Comment that Reimbursement Should be Provided to All Living Donors Without Regard to the Financial Situation of the Donor or Recipient

Four respondents commented that reimbursement should be available to all living organ donors regardless of their financial situation. The authorizing statute prohibits HRSA

from providing reimbursement to living organ donors if it is reasonable to expect the donor will receive reimbursement for these expenses from other sources, including the recipient of the organ. Thus, HRSA is required to establish criteria to assess the donor's ability to be reimbursed from these sources. Therefore, HRSA is maintaining these criteria with regard to donors eligible for reimbursement.

IV. Response to Concern that Financial Burden Is Not Adequately Addressed for Situations Where Donor and Recipient Reside in Same Household

Three commenters suggested that the Program does not adequately address the financial hardship often experienced when the donor and recipient reside in the same household and incur expenses and potential loss of income as a result of their surgeries. HRSA acknowledges the importance of ensuring that the Program consider the financial hardship that some households may experience as a result of living organ donation. HRSA is open to working with the recipient of the cooperative agreement to ensure that the Program's process for requesting consideration of financial hardship is sufficient to meet the needs of these donor and recipient household pairs; however, HRSA does not believe that revision of the preference categories or eligibility criteria is warranted to address this concern.

V. Response to Comments that Program Is Insufficient and Should Be Restructured

Two commenters argued that the Program is ineffective at providing the necessary protections for living organ donors and is inferior to the efforts of another existing program. Further, these commenters suggest that HRSA consider restructuring the reimbursement activity to collaborate with the other existing effort, which, in the commenters' description, provides a broader array of support. HRSA appreciates the feedback and will continue to consider other models for possible future actions to support living organ donors. HRSA is

open to considering innovative approaches to this Program consistent with the provisions of the authorizing statute. To that end, HRSA notes that other entities, including the current recipient of the cooperative agreement referenced above, are eligible to compete for future cooperative agreements for the operation of the Program. Those entities are encouraged to submit proposals when the opportunity becomes available.

VI. Other Issues

No commenters expressed concern about HRSA's proposed revisions to the eligibility criteria to clarify that travel and subsistence expenses incurred by non-directed living organ donors qualify as reimbursable expenses under the Program. Nor did HRSA receive comments expressing concern about revisions to the background section to ensure that the information aligns with the Program's legislative authority and that the guidelines would apply to the Program regardless of the recipient of the cooperative agreement that administers the Program. These changes to the guidelines will be finalized as proposed.

Inclusion of Additional Qualifying Expenses

Elsewhere in this issue of the Federal Register, HHS is publishing a final rule that expands the scope of reimbursable expenses incurred by living organ donors to include lost wages and child-care and elder-care expenses. This is the first time the Secretary determined that certain categories of "incidental non-medical expenses" incurred toward living organ donation are appropriate for reimbursement under this Program. In the notice of proposed rulemaking proposing to amend the Organ Procurement and Transplantation Network (OPTN) Final Rule to permit these expenses as "incidental non-medical expenses," HHS clarified that reimbursement for such expenses is not "valuable consideration" for purposes of section 301 of NOTA 84 FR 70139 (Dec. 17, 2019). Thus, such payments do not violate

the criminal prohibition against the exchange of valuable consideration for organs for use in transplantation.

This notice also revises the Program Eligibility Guidelines to incorporate these new qualifying expenses finalized through the OPTN Final Rule. Among other clarifying updates, a section has been added to the Guidelines to provide that qualifying expenses also include lost wages, child-care expenses, and elder-care expenses incurred by the donor and/or his/her accompanying or assisting person(s) as part of:

1. Donor evaluation and/or
2. Hospitalization for the living donor surgical procedure, and/or
3. Non-hospital post-surgery recovery time, and/or
4. Medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure (or beyond the 2-year period if exceptional circumstances exist).

Conclusion:

HRSA has reviewed and considered all comments in response to the March 31, 2020, notice and has determined that no additional modifications of the eligibility criteria proposed in that notice are warranted at this time. HRSA is also incorporating changes to the Guidelines to include lost wages, child-care expenses, and elder-care expenses as qualifying expenses under the Program, in accordance with the final rule published elsewhere in this issue of the Federal Register.

HRSA will continually monitor the effectiveness of the Program and the availability of funds for the Program. The final eligibility criteria are included in this document.

LIVING ORGAN DONATION REIMBURSEMENT PROGRAM ELIGIBILITY

GUIDELINES AS AMENDED

Section 3 of the Organ Donation and Recovery Improvement Act, 42 U.S.C. 274f, establishes the authority and legislative parameters to provide qualifying expenses incurred towards living organ donation. HRSA provides this support to living organ donors through the Living Organ Donation Reimbursement Program (formerly Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program) herein referred to as the Program, administered through a cooperative agreement. As provided for in the statutory authorization, the Program is authorized to provide reimbursement only in those circumstances when payment cannot reasonably be covered by other specified sources of reimbursement.

The recipient of the cooperative agreement, under Federal law, cannot provide reimbursement to any living organ donor for listed qualifying expenses if the donor can receive reimbursement 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.

In 2007, in response to public solicitation of comments, a threshold of income eligibility for the recipient and the donor of the organ was set at 300 percent of the HHS Poverty Guidelines in effect at the time of the eligibility determination. Pursuant to section 8 of Executive Order 13879, “Advancing American Kidney Health” (July 10, 2019) and feedback from the organ donation and transplantation community, HRSA revised the

threshold of income eligibility for the recipient and the donor of the organ to 350 percent of the HHS Poverty Guidelines, in effect at the time of the eligibility determination. HRSA assumes that recipients whose income exceeds this level will have the ability to reimburse the living organ donor for the travel, subsistence, and other incidental non-medical expenses authorized by the Secretary of HHS.

HRSA provides an exception to this rule for financial hardships. A transplant social worker or appropriate transplant center representative, based on a complete recipient evaluation, can provide an official statement, notwithstanding the recipient's income level, that the recipient of the organ would face significant financial hardship if required to pay for the qualifying living organ donor expenses. A recipient's financial hardship is defined as circumstances in which the recipient's income exceeds 350 percent of the HHS Poverty Guidelines in effect at the time of the eligibility determination, but the individual will have difficulty paying the donor's expenses due to other significant expenses. Determination of hardship in a particular case requires a fact-specific analysis; examples of significant expenses include circumstances such as paying for medical expenses not covered by insurance or providing significant financial support for a family member not living in the household (e.g., elderly parent). Waiver requests by the transplant center, on behalf of the donor, shall be made in writing and shall clearly describe the circumstances for the waiver request. The recipient of the cooperative agreement will review waiver requests and make a recommendation to HRSA to either approve or deny the request. HRSA will make the final determination and communicate its final determination to the recipient of the cooperative agreement. HRSA's determination will not be subject to appeal.

All persons who wish to become living organ donors are eligible to receive

reimbursement for their qualifying expenses if they cannot receive reimbursement from the sources outlined above and if all the requirements outlined in the *Criteria for Donor Reimbursement Section* are satisfied. However, because reimbursement is subject to the availability of funds, prospective living organ donors who are most likely not able to cover these expenses will receive priority. The ability to cover these expenses is determined based on an evaluation of (1) the donor and recipient's income, in relation to the HHS Poverty Guidelines and (2) financial hardship. As a general matter, income refers to the donor or recipient's total household income.

A donor may also be able to demonstrate financial hardship, even if the donor's income exceeds 350 percent of the HHS Poverty Guidelines if the donor will have difficulty paying the qualifying expenses due to other significant expenses. Although all requests will be reviewed on a case-by-case basis, examples of significant expenses include circumstances such as providing significant financial support for a family member not living in the household (e.g., elderly parent), and loss of income due to donation process. Waiver requests by the transplant center, on behalf of the donor, shall be made in writing and shall clearly describe the circumstances for the waiver request. The recipient of the cooperative agreement will review waiver requests and make a recommendation to HRSA to either approve or deny the request. HRSA will make the final determination and communicate its final determination to the recipient of the cooperative agreement. HRSA's determination is not subject to appeal.

Donors meeting the criteria for reimbursement will be given preference in the following order of priority, with non-directed donors placed in a category based solely on the donor's income:

Preference Category 1: The donor's income and the recipient's income are each 350 percent or less of the HHS Poverty Guidelines in effect at the time of the eligibility determination in their respective states of primary residence.

Preference Category 2: Although the donor's income exceeds 350 percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination, the donor demonstrates financial hardship. The recipient's income is at or below 350 percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination.

Preference Category 3: Any living organ donor, regardless of income or financial hardship, if the recipient's income is at or below 350 percent of the HHS Poverty Guidelines in effect in the recipient's State of primary residence at the time of the eligibility determination.

Preference Category 4: Any living organ donor, regardless of income or financial hardship, if the recipient (with income above 350 percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination) demonstrates financial hardship.

The recipient of the cooperative agreement will accept and process applications beginning with Preference Category 1. The recipient of the cooperative agreement will inform participating transplant programs directly and the public via its website whenever funding levels allow it to accept and/or process applications under additional preference categories.

The HHS Poverty Guidelines for 2020 are located at 85 FR 3060 (January 14, 2020).

Criteria for Donor Reimbursement

1. Any individual who in good faith incurs travel and other qualifying expenses toward the intended donation of an organ.
2. Donor and recipient of the organ are U.S. citizens or lawfully present in the U.S.
3. Donor and recipient have primary residences in the U.S. or its territories.
4. Travel is originating from the donor's primary residence.
5. Donor and recipient certify that they understand and are in compliance with Section 301 of NOTA (42 U.S.C. 274e) which states in part that it shall be 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. The transplant center where the donation procedure occurs certifies to its status of good standing with the OPTN.

Qualifying Expenses

For the purposes of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, *qualifying expenses* include

- I. Travel, lodging, meals and incidental expenses 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 (or beyond the 2-year period if exceptional circumstances exist).

- II. Lost wages, child-care expenses, and elder-care expenses incurred by the donor and/or his/her accompanying or assisting person(s) as part of:
- (1) Donor evaluation and/or
 - (2) Hospitalization for the living donor surgical procedure, and/or
 - (3) Non-hospital post-surgery recovery time, and/or
 - (4) Medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure (or beyond the 2-year period if exceptional circumstances exist).

The recipient of the cooperative agreement will pay for a total of up to five trips; three for the donor and two for accompanying persons. However, in cases in which the transplant center requests the donor to return to the transplant center for additional visits as a result of donor complications or other health related issues, the recipient of the cooperative agreement may provide reimbursement for the additional visit(s) for the donor and an accompanying person. The accompanying persons need not be the same in each trip.

Reimbursement for travel, lodging, meals, and incidental expenses, as appropriate, shall be provided at the Federal per diem rate, except for hotel accommodation, which shall be reimbursed at no more than 150 percent of the Federal per diem rate.

Donors may receive up to four weeks of reimbursement for lost wages, child-care expenses, and elder-care expenses associated with the surgery and recovery time. In addition, donors may receive reimbursement for up to two additional weeks for lost wages, child-care expenses, and elder-care expenses if the donor requires follow-up visits and hospitalization as a result of donor complications or other health related issues.

Reimbursement for lost wages is based on the donor providing appropriate

documentation, such as pay stubs, to the program. Reimbursement of lost wages is not limited to traditional wage rate income. Donors may receive reimbursement for non-traditional or irregular income through the program if they provide sufficient documentation of the expected lost wages.

In order to qualify for reimbursement of child-care expenses and elder-care expenses, a donor shall have caretaker responsibilities for:

- (1) A minor child and/or
- (2) An elder who requires caretaker assistance.

Caretaker responsibilities are not limited to familial relationships between the donor and/or the accompanying or assisting person(s), and the aforementioned individuals.

In considering requests for reimbursement for child-care expenses and elder-care expenses, the recipient of the cooperative agreement is encouraged to adopt a consistent application of “child” and “elder.” The recipient of the cooperative agreement may consider applicable laws within the jurisdiction in which the caretaker resides in reviewing requests for reimbursement for expenses for care of a “child,” and, in reviewing requests for reimbursement for elder-care expenses, may consider “elder” to refer to an individual age 60 and older, consistent with the Older Americans Act, 42 U.S.C. 3002(40).

Requests for reimbursement for the expenses of persons accompanying or assisting the donor for travel, housing, meals, and incidental expenses are considered under the preference categories and processed for reimbursement at the same time as requests for reimbursement for expenses incurred by the donor. Requests for reimbursement for the expenses of persons accompanying or assisting the donor for lost wages, child-care expenses,

and elder-care expenses are considered under the preference categories and will be processed separately. Requests for these expenses will be processed after all requests for expenses incurred by the donor, and expenses for persons accompanying or assisting the donor for qualifying expenses for travel, housing, meals, and incidental expenses, have been processed under all four preference categories.

The total Federal reimbursement for all qualifying expenses during the donation process shall not exceed \$6,000.

For donor and recipient pairs participating in a paired exchange program, the applicable eligibility criteria for the originally intended recipient shall be considered for the purpose of reimbursement of qualifying donor expenses even though the final recipient of the donated organ may not be the recipient identified in the original donor-recipient pair.

Given that non-directed donors have served as catalysts in transplant chains of multiple recipients, they are considered donating individuals eligible to receive reimbursement for qualifying expenses, if all other relevant program requirements are satisfied. In applying the preference categories to non-directed donors, the recipient of the cooperative agreement will review the household income of the non-directed donor against the current income threshold in effect at the time of the eligibility determination.

Maximum Number of Prospective Donors per Recipient

- *Kidney*: one donor at a time with a maximum of three donors
- *Liver*: one donor at a time with a maximum of five donors
- *Lung*: two donors at a time with a maximum of six donors

Special Provisions

Many factors may prevent the intended and willing donor from proceeding with the donation. Circumstances that would prevent the transplant or donation from proceeding include: Present health status of the intended donor or recipient, perceived long-term risks to the intended donor, justified circumstances such as acts of God (e.g., major storms or hurricanes), or a circumstance when an intended donor proceeds toward donation in good faith, subject to a case-by-case evaluation by the recipient of the cooperative agreement, but then elects not to pursue donation. In such cases, the intended donor and accompanying persons may receive reimbursement for qualifying expenses incurred as if the donation had been completed. The recipient of the cooperative agreement will file a form with the Internal Revenue Service reporting funds disbursed as income for expenses not incurred.

Dated: September 15, 2020.

Thomas J. Engels,

Administrator.

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