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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living
Organ Donation Proposed Eligibility Guidelines and Publication of Final
Program Eligibility Guidelines

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

ACTION: Response to Solicitation of Comments and Publication of Final
Program Eligibility Guidelines.

SUMMARY: A notice was published in the Federal Register on April 9,
2007 (72 FR 17564). The purpose of this notice was to solicit comments
on the eligibility criteria that were proposed by HRSA concerning the
Reimbursement of Travel and Subsistence Expenses Grant Program.

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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 travel and subsistence
expenses for living organ donors, with preference for those for whom
paying such expenses would create a financial hardship. On September
25, 2006, HRSA awarded a 4-year, \$8,000,000 Cooperative Agreement to
the Regents of the University of Michigan to establish 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 travel and related expenses
associated with the donation process. In addition, Congress requires
that funds from the Program not be used to reimburse travel and related
expenses associated with being a living 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.

On April 9, 2007, HRSA published a notice in the Federal Register,
requesting comments on the proposed eligibility criteria for the
Program. HRSA outlined that the two main issues raised in developing
program eligibility criteria are: (1) Criteria to identify potential
living organ donors who may be unable to pay for travel and subsistence
expenses associated with living organ donation, since Congress mandates
that these individuals be given priority for reimbursement; and (2)
criteria to assess the potential organ recipient's ability to pay for
these expenses incurred by the living organ donor, since Congress
prohibits reimbursement of these expenses if the recipient of the organ
can reasonably pay for these expenses. HRSA proposed 200 percent of the
HHS Poverty Guidelines as an income threshold for determining which
transplant recipients could reasonably be expected to pay for travel
and subsistence expenses incurred by the living donor. HRSA requested
comments as to whether this was a reasonable approach for assessing a
recipient's ability to pay. HRSA also proposed some additional criteria
governing donor reimbursement including: Good faith effort to become a
donor, U.S. legal status, donor informed consent, compliance with the
criminal provisions contained in section 301 of the National Organ
Transplant Act of 1984, as amended, concerning the transfer of a human
organ for valuable consideration and requirements of the transplant
program to be in good standing with the Organ Procurement and
Transplantation Network.

HRSA received 29 public comments from advocacy groups, transplant
hospitals, and concerned citizens. Nineteen of these comments expressed
dissatisfaction in limiting reimbursement to specific donors. The

majority of these respondents remarked that reimbursement should be available to all living donors without conditions. Three of these commenters proposed that HRSA increase the threshold to 300 percent of the HHS Poverty Guidelines. One respondent expressed concerns that the expectation of recipients paying for donors' costs and the income guidelines providing preference for the lowest socioeconomic class may result in the exchange of valuable consideration for the organ or otherwise be coercive towards individuals of lower socioeconomic status. Three respondents stated that they support the criteria as proposed. One of these two respondents stated that the Program should be based on the donor's ability to pay, that if people really want to donate and can afford it, money shouldn't be an issue.

One respondent asked HRSA to protect the rights of all living donors. Another respondent feels that HRSA is 'pushing' the black market by paying \$6,000, which is an insufficient amount, to living organ donors. Furthermore, this respondent feels that the Program,

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as outlined, is offensive to living donors and that no Program would be better than the Program that is proposed. None of the respondents explicitly addressed the criteria for donor reimbursement or qualifying expenses.

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 That Reimbursement Should Be Provided to All Living Donors Without Regard to the Financial Situation of the Donor or Recipient

Most respondents commented that reimbursement should be available to all living donors regardless of their financial situation. The authorizing statute requires HRSA to give preference to individuals for whom paying for the travel and subsistence expenses in the donation process would be financially burdensome. Another restriction bars HRSA from making funds available for reimbursement to living donors whenever it is reasonable to expect the donor to 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. Based on these restrictions 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 the use of the HHS Poverty Guidelines satisfies these legislative requirements.

II. Response to Comment To Increase the Income Threshold to 300 Percent of the HHS Poverty Guidelines

In addition to the 19 respondents who believe that reimbursement should be available to all living donors, three respondents proposed that HRSA increase the income threshold to 300 percent of the HHS Poverty Guidelines for both donors and recipients. After further deliberations, HRSA accepted this recommendation. Individuals in need of a transplant face many financial obligations such as direct medical expenses, insurance co-pays, medications, etc., associated with end-stage organ failure. Similarly, potential donors face the potential loss of income and other expenses that may increase as a result of the donation. It is the hope of HRSA that this change will help to ease the burden for both donors and recipients.

III. Response to Concern Over Expectation by the Organ Donor That Recipient Should Pay Donor's Expenses

One respondent expressed concerns about the expectation that the recipient pay for the donor's expenses. As stated previously, the authorizing statute requires that HRSA consider the recipient's ability to pay.

IV. Response to Comment That All Organ Donors Deserve This Gift for Their Sacrifice

The majority of respondents commented that all donors should receive reimbursement under this Program. The most frequent reason stated was that donors deserve this gift for their sacrifice. The authorizing legislation does not intend the payment authorized under this program to be a gift or recognition for the sacrifice of the donor or as an enticement to donate. The intent is to ease the financial burden on those individuals who make the altruistic decision to donate and to give priority to those who have no other available sources to

pay for travel and subsistence expenses associated with the donation.

V. Response to Comment That Overall Reimbursement Level Should Exceed \$6,000

Eight respondents mentioned the \$6,000 level in their comments. HRSA wishes to clarify that \$6,000 is the ceiling or reimbursement cap for each donor participating in the Program. The Program will provide reimbursement for only the qualifying expenses outlined in the final eligibility criteria. The eligibility criteria provide more details on qualifying expenses.

Conclusion

HRSA has reviewed and considered all comments and has revised certain eligibility criteria as appropriate. HRSA will continually monitor the progress of the Program grantee, the Regents of the University of Michigan, to ensure that it adheres to the Program eligibility criteria in the operation of the National Living Donor Assistance Center. The final eligibility criteria are included in this document. The final eligibility criteria guidelines document is also available at <http://www.livingdonorassistancecenter.gov>.

National Living Donor Assistance Center (NLDAC) Program Eligibility Guidelines

Section 3 of the Organ Donation and Recovery Improvement Act (ODRIA), 42 U.S.C. 274f, establishes the authority and legislative parameters to provide reimbursement for travel and subsistence expenses incurred towards living organ donation. HRSA awarded a cooperative agreement to the Regents of the University of Michigan (Michigan), which partnered with the American Society of Transplant Surgeons (ASTS), to establish the National Living Donor Assistance Center (NLDAC) to operate this Program.

As provided for in the statutory authorization, this Program is intended to provide reimbursement only in those circumstances when payment cannot reasonably be covered by other sources of reimbursement. The NLDAC, under Federal law, cannot provide reimbursement to any living organ donor for travel and other 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 response to public solicitation of comments, a threshold of income eligibility for the recipient of the organ is 300 percent of the Department of Health and Human Services (HHS) Poverty Guidelines in effect at the time of the eligibility determination. The Program assumes that recipients whose income exceeds this level will have the ability to reimburse the living organ donor for the travel and subsistence expenses and any other qualifying expenses that can be authorized by the Secretary of HHS. The Program 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 300 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. Whether or not hardship exists 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

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transplant center, on behalf of the donor, shall be made in writing and shall clearly describe the circumstances for the waiver request. The NLDAC 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 NLDAC. The NLDAC will notify the transplant center of the final determination. 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 travel and qualified 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 of the limited funds available, prospective living 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 (described in Table 1.1 below), and (2) financial hardship. As a general matter, income refers to the donor or recipient's total household income. A donor may be able to demonstrate financial hardship, even if the donor's income exceeds 300 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), 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 NLDAC 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 NLDAC. The NLDAC will notify the transplant center of the final determination. HRSA's determination will not be subject to appeal.

Donors will be given preference in the following order of priority:

Preference Category 1: The donor's income and the recipient's income are each 300 percent or less of 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 300 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 300 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 300 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 300 percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination) demonstrates financial hardship.

HRSA reserves the right to prioritize those most in financial need (based on income or other specified factors) if it receives large numbers of applications concerning donors meeting preference category 1.

The HHS Poverty Guidelines for 2007 (Federal Register, Vol. 72, No. 15, January 24, 2007, pp. 3147-3148) are shown in the table below.

2007 HHS Poverty Guidelines

Persons in family or household	48 Contiguous States and DC	Alaska	Hawaii
1.....	\$10,210	\$12,770	\$11,750
2.....	13,690	17,120	15,750
3.....	17,170	21,470	19,750
4.....	20,650	25,820	23,750
5.....	24,130	30,170	27,750
6.....	27,610	34,520	31,750
7.....	31,090	38,870	35,750
8.....	34,570	43,220	39,750
For each additional person, add.....	3,480	4,350	4,000

Source: Federal Register, Vol. 72, No. 15, January 24, 2007, pp. 3147-3148. These guidelines are updated periodically.

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 admitted residents of 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 ``* * * 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 Organ Procurement and Transplantation Network (OPTN).

Qualifying Expenses

For the purposes of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, qualifying expenses presently include only travel, lodging, and meals and incidental expenses incurred by the donor and/or his/her accompanying person(s) as part of:

- (1) Donor evaluation, clinic visit or hospitalization,
- (2) Hospitalization for the living donor surgical procedure, and/or

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(3) Medical or surgical follow-up clinic visit or hospitalization within 90 days following the living donation procedure.

The Program will pay for a total of up to five trips; three for the donor and two for accompanying persons. The accompanying persons need not be the same each trip.

The total Federal reimbursement for qualified expenses during the donation process for the donor and accompanying individuals shall not exceed \$6,000.00. Reimbursement for qualifying expenses 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.

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.

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 NLDAC, but then elects not to pursue donation. In such cases, the intended donor and accompanying persons may receive reimbursement for qualified expenses incurred as if the donation had been completed. Under Program policy, a form will be filed with the Internal Revenue Service (IRS) reporting funds disbursed as income for expenses not incurred.

Dated: October 1, 2007.

Elizabeth M. Duke,
Administrator.

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