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 [Notices]
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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 Eligibility Guidelines

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

ACTION: Response to solicitation of comments on amendment to program
 follow-up period and publication of amended Program Eligibility
 Guidelines.

 SUMMARY: This notice finalizes an amendment to the eligibility
 guidelines proposed on March 4, 2009 in the Federal Register (74 FR
 9407). The purpose of this notice was to solicit comments on the
 amendment to the Program Eligibility Guidelines proposed by HRSA
 concerning the Reimbursement of Travel and Subsistence Expenses Program
 follow-up period.

FOR FURTHER INFORMATION CONTACT: Richard Durbin, Director, Division of
 Transplantation, Healthcare Systems Bureau, Health Resources and
 Services Administration, Parklawn Building, Room 12C-06, 5600 Fishers
 Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301)
 594-6095; or E-mail: rdurbin@hrsa.gov.

SUPPLEMENTARY INFORMATION: In the existing Program eligibility
 guidelines, under the Qualifying Expenses Section, the first paragraph
 states:

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

HRSA proposed amending the first bullet of this paragraph to read:
 ``(1) Donor evaluation, and/or''. In addition, HRSA proposed amending
 the third bullet of this paragraph to read: ``(3) Medical or surgical
 follow-up clinic visit or hospitalization within two calendar years or
 beyond--if exceptional circumstances exist--following the living
 donation procedure.'' The purpose of this proposed change was to bring
 the NLDAC follow-up period in line with the OPTN policies of a 2-year
 follow-up of living organ donors.

HRSA received six public comments on this request. All the
 respondents

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support HRSA's proposed amendment. HRSA wishes to thank everyone who
 reviewed this request even if a formal response was not sent to HRSA.

Through this notice, HRSA approves the amendment to the
 Reimbursement of Travel and Subsistence Expenses Program Eligibility
 Guidelines as published in the Federal Register. This document also
 corrects a mistake included in the previous version of the Guidelines
 concerning the proper decision-maker on financial hardship
 determinations. Finally, HRSA notes that the grantee has the authority
 to make operational decisions in implementing the Program, such as
 setting filing deadlines.

The amended eligibility criteria are included in this document. The
 amended eligibility criteria guidelines document is also available at
<http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.livingdonorassi>

National Living Donor Assistance Center (NLDAC) Program Eligibility
 Guidelines as Amended

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 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 NDLAC 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 NDLAC 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 for the grantee 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 2009 (Federal Register, Vol. 74, No. 14,

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January 23, 2009, pp. 4199-4201) are shown in the table below.

2009 HHS Poverty Guidelines

Persons in family or household	48 Contiguous States and DC	Alaska	Hawaii
1.....	\$10,830	\$13,530	\$12,460
2.....	14,570	18,210	16,760
3.....	18,310	22,890	21,060
4.....	22,050	27,570	25,360
5.....	25,790	32,250	29,660
6.....	29,530	36,930	33,960
7.....	33,270	41,610	38,260
8.....	37,010	46,290	42,560
For each additional person, add.....	3,740	4,680	4,300

Source: Federal Register, Vol. 74, No. 14, January 23, 2009, pp. 4199-4201.

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 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).

The Program 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, NLDAC 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.

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: June 10, 2009.

Mary K. Wakefield,

Administrator.

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