



April 29, 2020

Via E-mail

Frank Holloman, Director
Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 08W53A
Rockville, Maryland 20857

RE: Health Resources and Services Administration: Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program Eligibility Guidelines (85 FR 17894)

Dear Mr. Holloman:

On behalf of the American Society of Transplantation (AST), representing over 4,300 members of the nation's medical professionals engaged in the field of solid organ transplantation, we applaud HRSA's efforts to expand coverage of living organ donor Program eligibility guidelines. As organ transplant candidates die every day awaiting an organ, removing barriers to living organ donation will help increase the number of organs available for transplant.

Transplantation creates a better quality of life for most, allowing them to return to work and other activities. Living donor transplantation saves lives, often providing the very best possible outcome for the recipient. The growing disparity between the number of patients in need of transplantation and availability of transplantable organs has increased interest in living donors. Innovative approaches have been developed to increase numbers of living donors, including use of non-directed donors, paired donation, and immunologic conditioning of recipients to allow the successful transplantation between previously incompatible donor-recipient pairs. At the same time, there is increasing interest in the risks (medical and psychosocial) living donors accept to benefit others, and in ensuring appropriate protection (short- and long-term) for those who choose to donate.

With the current Administration's focus on kidney health and transplant through the American Kidney Health Initiative, it is critical that every step be made to meet the laudable goal of doubling kidney transplants by 2030. The changes put forth by HRSA

NATIONAL OFFICE

American Society of Transplantation
1120 Route 73, Suite 200 • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.581.9604
info@myAST.org • myAST.org

GOVERNMENT RELATIONS

William Applegate, Director of Government Relations
Bryan Cave Leighton Paisner LLP
1155 F Street, NW • Washington, DC 20004
202.258.4989 • bill.applegate@bcplaw.com

to administer these funds, currently through the National Living Donor Assistance Center (NLDAC), to expand eligibility criteria will help, but the AST believes that it should be expanded even further to maximize the number of living donors without their having to incur costs to donate.

The current proposal seeks to:

- Revise the eligibility threshold to cover applicants living in nearly 70% of US households;
- Clarify use of the existing preference categories in relation to the proposed income eligibility threshold; and
- Amend the qualifying expense section to allow for reimbursement for eligible non-directed donors.

Revising Eligibility Threshold

Ideally, we believe that the elimination of recipient household income as part of “means testing” eligibility for donor reimbursement based on this premise is critical. The AST strongly believes that no living organ donor should incur costs associated with donation; rather that this should be a cost neutral event for the donor.

The AST appreciates the HRSA recommendation to increase the eligibility threshold from 300% from 350% to cover more American households, but questions whether this incremental change will have the desired impact. The Society is enthusiastically in support of the ACOT’s recommendations to move to an eligibility threshold of 500% of the 2020 HHS Poverty Guideline for a family of four, which would include a household income of up to \$131,000. As previously stated, we believe that no living organ donor should incur costs associated with donation, but this 500% threshold would create a more reasonable first step to achieving this goal by the inclusion of more American families who may be otherwise able to give the gift of life.

We recommend that the income eligibility threshold be reviewed annually and increased by 50% after every year where less than 90% of the allocated funds are used for living donors. Alternatively, the threshold could be reduced by 50% after any year where the allocated funds were used in full sooner than 9 months into the fiscal year.

The current statute governing this Program does not allow for paying of donor expenses if the organ recipient can be reasonably expected to be cover them. HRSA requests feedback regarding whether this should remain tied to the Program’s eligibility threshold. The AST feels strongly that the income eligibility threshold should apply to

the living donor only. A number of publications^{1, 2, 3} have already shown that, on average, the recipient's income is lower than that of the donor. This is understandable, considering that many awaiting an organ transplant are too ill to work full time.

The AST strongly recommends that the threshold should apply to the living donor, and not the recipient. We believe there is an alternate method for meeting the criteria called for in Section 377 of the Public Health Service (PHS) Act, 42 U.S.C. § 274f:

42 U.S. Code 274f

(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program;

(2) by an entity that provides health services on a prepaid basis; or

(3) by the recipient of the organ.

Finally, based on publications, we understand that fewer than 10% of living donors have historically accessed the NLDAC funds. It appears that education and awareness regarding this resource may be just as necessary as the threshold increase to help this program meet its goal. It is unclear whether those who may benefit from the NLDAC program are limited by health literacy or ability to navigate the application requirements. We suggest that at least a portion of the unused funds each year be allocated for educational resources that can be more broadly shared with physicians, dialysis clinics, and transplant programs to encourage participation in this program when considering living donation.

¹ Gill JS, Gill J, Barnieh L, Dong J, Rose C, Johnston O, Tonelli M, Klarenbach S. Income of living kidney donors and the income difference between living kidney donors and their recipients in the United States. *Am J Transplant.* 2012; 12:3111-8.

² Gore JL, Singer JS, Brown AF, Danovitch GM. The socioeconomic status of donors and recipients of living unrelated renal transplants in the United States. *J Urol.* 2012; 187:1760-5.

³ Rodrigue JR, Schold JD, Morrissey P, Whiting J, Vella J, Kayle LK, Katz D, Jones J, Kaplan B, Fleishman A, Pavlakis M, and Mandelbrot DA. Direct and Indirect Costs Following Living Kidney Donation: Findings from the KDOC Study. *American Journal of Transplantation* 2016; 16: 869–876.

Clarify the use of Existing Preference Categories

If the thresholds are tied to donor's eligibility and not the recipient's, the current categories are no longer applicable. The AST suggests the following new categories for consideration:

- Category 1 – donor applicant who meets income criteria with no external support for qualifying expenses (i.e. from any compensation program, insurance policy, recipient, or other entity)
- Category 2 – donor applicant who meets income criteria with partial external support for qualifying expenses.

We see any preference categories as ultimately irrelevant, as the AST strongly believes that no donor should incur costs associated with donation; rather that this should be a cost neutral event for the donor.

Amend Qualifying Expenses to Allow Eligible Non-Directed Donor Reimbursements

The AST firmly supports allowing eligible non-directed donors to qualify for reimbursable travel and subsistence expenses as outlined for this Program.

This also complements the earlier recommendation of the application process being driven by living donor qualifications rather than that of the recipient. This would allow for streamlining within the Program itself rather than having separate pathways for qualification.

Revisions to Program Eligibility Guidelines

The AST supports revisions that will ensure that information aligns with the Program's legislative authority and eliminates the need to revise eligibility guidelines in the event of a change to the awardee of the cooperative agreement.

Finally, we recommend that the Background section of the current NLDAC website be amended to be more inclusive of non-directed living donors:

"Many individuals may want to become living donors for family or acquaintances, but lack the necessary resources to cover transplant related expenses not covered by insurance or other sources."

The AST appreciates this opportunity to provide feedback regarding this notice and appreciates HRSA's efforts provide additional support to living donors. We hope that this, in turn, will lead to the increase of living donor transplants and a reduction of the

number of those on the organ transplant wait list. We recognize that some of the recommendations we offer here are outside of the purview of HRSA and would require legislative changes. The Society feels strongly that all living donors should receive reimbursement for travel and subsistence rather than incurring these costs to donate- not just those with limited financial means. If you have questions regarding this response, please direct them to Shandie Covington, our Executive Director, at scovington@myast.org or 856-316-0924.

Respectfully,

A handwritten signature in black ink, appearing to read "Emily Blumberg". The signature is fluid and cursive, with the first name "Emily" and last name "Blumberg" clearly distinguishable.

Emily A. Blumberg, MD
President