April 21, 2020

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 (the "Program Notice")

Dear Mr. Holloman:

On behalf of the American Society of Transplant Surgeons (ASTS), I am extremely pleased to have the opportunity to comment on the Program Notice. ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy. ASTS, as a subcontractor on the Health Resources and Services Administration (HRSA) Program grant ("Reimbursement of Travel and Subsistence Expenses for Living Organ Donation"), has a deep understanding of the barriers to living organ donation and the positive impact the grant funding has on living donation.

We applaud HRSA for its efforts to expand the reach of the Program and for taking steps to improve existing financial barriers for living donors. Our experience as a NLDAC subcontractor suggests that expanding the eligibility criteria has the potential to significantly increase living donation – an increase that is particularly critical in light of the ongoing deceased donor shortage and is necessary if kidney transplants are to double by 2030, consistent with the goal established by the American Kidney Health Initiative announced by the Administration earlier this year.

Living donor transplantation is not only clinically superior to all other treatment modalities (including deceased donor transplantation) but is also extraordinarily cost effective. Few other clinical interventions so effectively deliver superior clinical results at a substantial cost saving. It is important to emphasize that the budget allocated to addressing these financial barriers for living donors yields massive savings to the Government as the primary payer for dialysis services under Medicare's ESRD program. For example, a study[1] based on 2012- 2015 data from NLDAC, the United States Renal Data System, and the Scientific Registry of Transplant Recipients

[1] Mathur AK, Xing J, Dickinson DM, et al. Return on investment for financial assistance for living kidney donors in the United States. *Clin Transplant*. 2018;32:e13277. https://doi.org/10.1111/ctr.13277.

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suggests that Return on Investment on the Program varies from 5.1- fold (1- year) to 28.2- fold (5- year) and that the Program resulted in $256 million in projected Medicare savings over five years. For this reason, targeted efforts to expand the reach of the Program have the potential not only to improve the lives of those with ESRD, but also to result in significant Medicare savings.

I. Comments on the use of Financial Eligibility Criteria to Evaluate Recipient Ability to Pay

After noting that the authorizing statute precludes the Program from paying for donor expenses if those expenses reasonably can be expected to be covered by an organ recipient, the Notice solicits comments on:

> whether an organ recipient's reasonable ability to pay for a donor's expenses should remain tied to the Program's income eligibility threshold . . .

While we understand that the governing statute precludes Program payment for donor expenses if the recipient can reasonably be expected to pay for those expenses, we have grave reservations about establishing financial criteria for recipients. The requirement that Program eligibility be determined based in part on the financial means of the recipient is, in our view, misguided and ethically questionable. As noted in several publications,[2] the recipient's annual household income – on average – is lower than that of donors. Six percent of donors receive any type of financial assistance from their recipient, based on recent multi-center data, so (a) it is unreasonable to expect recipients who are also financially challenged by their chronic illness and transplant surgery/recovery (and likely out of work incurring lost wages themselves) to financially support their donors, and (b) it appears that this requirement deters potential donors from even applying for NLDAC assistance. For this reason, **ASTS believes that the recipient's household income should be removed from Program eligibility criteria altogether, and Program distributions should be based solely on whether a potential living donor is experiencing financial barriers that would otherwise preclude donation.**

Moreover, even if HRSA believes that the statutory language requires some inquiry into recipient finances, we do not believe that it is necessary or prudent to interpret this statutory provision to require the adoption of strict recipient income or financial hardship eligibility guidelines. This approach is administratively burdensome and unnecessarily intrusive, placing transplant centers in a position of examining their patients' highly personal financial information and requiring the Program to conduct periodic audits of transplant programs' income eligibility processes. We suggest that HRSA instead consider less intrusive and more easily administrable alternatives, including, for example:

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[2] 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.

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.

J. R. Rodrigue, J. D. Schold, P. Morrissey, J. Whiting, J. Vella, L. K. Kayle, D. Katz, J. Jones, B. Kaplan, A. Fleishman, M. Pavlakis and D. A. Mandelbrot . Direct and Indirect Costs Following Living Kidney Donation: Findings From the KDOC Study. American Journal of Transplantation 2016; 16: 869–876.

- Requiring transplant recipients to attest that covering donor expenses would result in a financial hardship and therefore satisfy the statutory requirement;
- Automatically considering Medicaid recipients, Supplement Security Income (SSI) recipients, and recipients of other forms of public assistance to meet the statutory criteria;
- Automatically considering any recipient who pays Medicare's standard Part B premium to meet the statutory standard. In this regard, we note that Medicare premiums are based on the beneficiary's modified adjusted gross income, or MAGI, defined as the beneficiary's total adjusted gross income plus tax-exempt interest (based on most recent available IRS data). HRSA may wish to consider any Medicare beneficiary who pays the standard Medicare premium to be eligible for the Program.[3]

Unfortunately, increasing the threshold from 300% to 350% of the Federal Poverty Level (FPL) is insufficient to meet Program goals. Raising the income eligibility threshold from 300% to 350% of FPL will increase the percentage of potential donors eligible for the Program only from 61% to 67%. **We encourage the use of a 500% FPL threshold for program eligibility, as recommended by ACOT, which would cover 81% of US households. This would likely address needs of a larger proportion of the donor population and still reasonably respect budgetary limitations.**

II. Comments on Non-Directed Donors

ASTS strongly supports updating eligibility requirements to allow travel/subsistence cost support for all non-directed donors. Non-directed donors maximize the utility of living donation: Organs from non-directed donors may trigger multiple living donor transplants if they are utilized to begin a chain in a paired exchange model. Thus, supporting a non-directed donor can be a "force multiplier" in achieving cost savings and facilitating as many transplants as possible**. For these reasons, as well as those set forth in the Notice, we strongly support eliminating the application of the recipient financial threshold in the case of non-directed donors.**

III. Clarification of Preference Categories for the Prioritization of Program Distributions

We believe that requiring public notice whenever a new preference category opens (or closes) has the potential to complicate, rather than simplify, Program operations. Preference category determinations should be made between the grantee and HRSA through the collaborative grant mechanism that is currently in place, rather than tying specific preference categories into federal regulation, especially since preference categories may change if HRSA implements a Program for payment of lost wages and child/eldercare expenses, as recently proposed.

The Program Notice accurately states current Program preference categories for prioritization of Program distributions. However, the Program Notice suggests that, in the future, it would be necessary for a public announcement to be made whenever the inclusion or exclusion of a preference category as an eligibility factor is planned. We believe that such a requirement has the potential to significantly complicate Program operations. Applications must be processed as expeditiously as possible after they are completed. At the same time, it is necessary to ensure both that Program funds remain available

[3]In 2020, Medicare beneficiaries whose MAGI is less than or equal to the "higher-income" threshold — $87,000 for an individual taxpayer, $174,000 for a married couple filing jointly — pays the "standard" Medicare Part B rate for 2020.

throughout the year and that all Program funds allocated are distributed to donors in need. The number of applications varies every month, requiring the Program to constantly balance all these factors in allocating Program funds. This calculation is likely to become even more complex if HRSA implements Program payments for lost wages, childcare, and elder care expenses.

Finally, ASTS also supports administrative language that clearly distinguishes the Program from the existing grantee, in concert with other HRSA rules.

Again, we appreciate the opportunity to comment on this Notice and applaud HRSA for taking action to expand the Program to facilitate increased living donor transplants in coming years. If you have any questions regarding ASTS' position on these issues, please do not hesitate to contact Daniel D. Garrett, ASTS Executive Director/CEO at Daniel.Garrett@asts.org or call 703-414-7870.

Sincerely yours,

Lloyd E. Ratner, MD, MPH, FACS
President
ASTS