July 27, 2026

Ms. Allison Hutchings
Division of Transplantation
Health Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Rockville, MD 20857

Submitted electronically via livingdonorsupport@hrsa.gov

Re: Comments on Federal Register Notice "Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response To Honor Our Living Donors Act"

Dear Ms. Hutchings:

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment on the proposed "Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response To Honor Our Living Donors Act" (the "Proposed Guidelines"). ASTS is a medical specialty society representing approximately 2,400 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, and we have long advocated for the removal of financial and other disincentives that pose a barrier to living donation.

The Living Organ Donation Reimbursement Program ("LODRP" or "the Program") is the only program available to living donors at all US transplant centers. The Program currently provides financial support to more than 20% of US living donors and thus plays a critical role in ensuring access to living donor transplantation.

ASTS serves as a key subcontractor and operational partner for the Program, which operates under a cooperative agreement from the Health Resources and Services Administration (HRSA). ASTS headquarters houses the operational arm of the program—the National Living Donor Assistance Center (NLDAC)—and, through NLDAC, ASTS administers federal grant funding to provide means-tested reimbursements to living organ donors for out-of-pocket costs, including transportation, lodging, meals, lost wages, and dependent care. As a key LODRP subcontractor in charge of administering disbursement of funds, we are in a unique position to provide feedback on the Proposed Guidelines.

ASTS applauds the HOLD Act's removal of the recipient's ability to pay from consideration in determining LODRP eligibility. The enactment of this legislation is the culmination of feedback from many stakeholders over many years, which established that limiting program eligibility based on recipient income has posed a significant barrier to appropriate use of the Program by

potential donors. We are hopeful that implementation of the HOLD Act will significantly enhance the role of the LODRP in reducing disincentives to donation for potential living donors.

While ASTS is in full agreement with the intent of the Proposed Guidelines—to ensure that LODRP funds are disbursed in a manner that provides support for those who need it most—we believe that adoption of the Categories and application review processes set forth in the Proposed Guidelines are likely to dissuade applications and increase NLDAC's administrative burden. In addition, implementation of the proposed process has the potential to reduce significantly the amount of overall financial support provided to potential living donors through the LODRP, leaving Program funds unexpended at the end of the year and at risk of reallocation to other HRSA priority projects.

In order to ensure that sufficient funds are available to support those living donors in greatest financial need, the Proposed Guidelines describes a progressive opening of applications to lower preference categories donors (i.e. to more well-off donors): Under the proposed process, only applications from Priority Category 1 donors (Household Income (HHI) less than or equal to 350% of HHS Poverty Guidelines) would be considered for the first six months of the year, and applications from those with HHI over 350% of the HHS Poverty Guidelines would be considered after that time only if the availability of support for Priority Category 1 would not be jeopardized by opening the application process to more well-off donors.

The proposal to delay consideration of donors with HHI over 350% of the HHS Poverty Guidelines appears to be driven by the concern that LODRP funds otherwise may run out by the end of the fiscal year, making support unavailable by the end of the year for those donors in the greatest financial need. We understand and concur with this concern; however, we note that LODRP funds historically have not been fully expended by the end of the fiscal year. While unexpended LODRP funding historically has been rolled over and made available in the following fiscal year, recent discussions with HRSA suggest that unexpended funds can be reallocated other programs, resulting in a net loss of support for living donors.

While it is possible that the elimination of recipient means testing may increase the number of living donors who qualify for support, leaving the LODRP bereft of funds at the end of the year, we note that, based on the most recent data available, this appears unlikely. Based on 2025 data, only approximately 5% of applications were denied based on recipient income. Research[1] indicates that there is rarely a significant differential between donor and recipient income, strongly suggesting that the focus on donor, rather than recipient income, is not likely to make LODRP funds significantly more likely to be depleted if donors, rather than recipients, are means tested. Anecdotally, it would appear that focusing on donor rather than recipient income has the potential to reduce, rather than increase, the number of applications that meet financial eligibility criteria, since the medical condition of those with end stage organ failure often renders potential recipients unable to work or depresses earnings, while potential donors must be in good health in order to donate.

Rather than implementing a system that delays acceptance of applications from Priority Category 2 donors, we recommend a system that authorizes processing of applications from all donor Categories and "funnels

[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 Nov;12(11):3111-8. doi: 10.1111/j.1600-6143.2012.04211.x. Epub 2012 Aug 6. PMID: 22882723.

Gill J, Dong J, Gill J. Population income and longitudinal trends in living kidney donation in the United States. J Am Soc Nephrol. 2015 Jan;26(1):201-7. doi: 10.1681/ASN.2014010113. Epub 2014 Jul 17. PMID: 25035519; PMCID: PMC4279742

down" acceptance of applications from more well-off donors if it appears that funds are being depleted at a rate that may leave insufficient amounts available for Category 1 donors by the end of the year. This allows for the neediest donors to be protected; establishes a system that is easily explained to the public, potential living donors and recipients; eliminates the potential need for duplicative donor evaluation and administrative expenses; and reduces the possibility that LODRP funds will be "left over" at the end of the year.

We believe that withholding available funds from anyone other than Category 1 donors based on the possibility that LODRP funds *may* run out is difficult to explain and justify to transplant program administrators, potential recipients, and potential donors, and is likely to result in confusion, resentment, and mistrust. Such a system places transplant center and NLDAC staff in the position of informing potential applicants that, if they apply during the first six months of the year, they may (or may not) be deemed ineligible based on their income, but if they wait until after a mid-year determination is made by HRSA and its contractor, they possibly may be considered for support. This system places a large proportion of potential living donors and recipients in the position of:

(a) foregoing potentially available Program support (which may be the only practicable option if immediate transplantation is clinically necessary);
(b) applying during the first six months of the year, hoping to meet the income requirements, and, if rejected, re-applying later in the year after the income restrictions are lifted (necessitating a new application and potentially necessitating duplicative testing due to the passage of time); or
(c) waiting to see if income restrictions are lifted later in the year, potentially compromising the recipient's health and testing the donor's continued commitment to the procedure.

This system would significantly compromise the accessibility of the program and increase administrative complexity. By contrast, a system that is open to all Categories at the beginning of the year and limits eligibility based on donor income as necessary to preserve support for those who need it most is much more easily explained and administered.

We also believe that, in the interests of clarity and to facilitate the processing of applications, Priority Category 2 should be broken down into two distinct categories: Priority Category 2 (comprising donors with HHI of 351-500% of HHS Poverty Guidelines) and Priority Category 3 (comprising donors with HHI of 501-750% of HHS Poverty Guidelines who are able to demonstrate financial hardship). Since those with HHI of 351% to 500% will not be required to submit information demonstrating financial hardship while those with higher HHI will be required to submit such information, the same application process cannot be used for both groups. An initial application that requires the submission of financial hardship information would impose unnecessary burdens on those with HHI of 351% to 500% of HHS Poverty Guidelines and dissuade applicants, while not requiring this information in the initial application will require staff to go through the applications of all Priority 2 donors, screen out those with income exceeding the 500% threshold, and require supplemental submissions from higher income donors—many of whom might not have applied at all had they fully understood that detailed financial information demonstrating financial hardship would be required.

In addition, creating a new Priority Category 3 for the highest income applicants would allow the LODRP to assign these applicants a lower priority than those with more moderate income whose income nonetheless exceeds the Priority Category 1 threshold. The separate categorization of the highest income donors would provide flexibility necessary to ensure that the LODRP funds appropriated by Congress are all distributed to potential donors. For example, if HRSA adopts the "funnel down" application processing procedures

proposed above, HRSA and the cooperative agreement recipient could agree mid-year to stop accepting applications from Category 3 donors but continue accepting applications from Category 2 donors. Likewise, even if our proposed "funnel down" application process is not adopted and only Category 1 donor applications are accepted for the first six months, HRSA and the cooperative agreement recipient could open the application process to Category 2 (but not Category 3) donors mid-year, depending on the financial status of the LODRP fund at the time.

Finally, we note that, under the Proposed Guidelines, recipient income information would continue to be collected from the donor for informational purposes. Because the eligibility criteria and the Organ Donation and Recovery Improvement Act require the recipient of the organ to complete part of the application, the recipient should be asked to provide the estimate of their own household income, not the donor. This will result in more accurate data and avoid creating awkwardness between donors and recipients, consistent with the intent of the HOLD Act. We appreciate that the Proposed Guidelines provide non-directed donors with the option to report "I don't know" on the question related to recipient income and believe that the Guidelines should explicitly state that non-directed donors need not provide this information to be eligible for support.

While we recognize that the *Federal Register* Notice setting forth the Proposed Guidelines solicits public comment on a narrow range of issues, ASTS looks forward to having the opportunity to comment on other much-needed LODRP policy changes, which we hope will be forthcoming in the near future. Most importantly, the maximum amount of support that may be provided to an applicant has been capped at $6,000 since 2007, and a request to increase the cap to $10,000 has been pending since 2022. We encourage HRSA to expedite approval of this increase— an increase that is critical to fully remove financial disincentives for living donors.

We appreciate the opportunity to comment on the Proposed Guidelines and look forward to continuing to support NLDAC's critical work. If you have any questions, or if we can be of any assistance, please do not hesitate to contact ASTS' Director, Advocacy and Professional Practices at Emily.Besser@ASTS.org.

Respectfully,

Henry B. Randall MD, MBA

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