

The American Society of Transplantation (AST), representing a majority of medical professionals engaged in the field of solid organ transplantation, applauds amendments to the National Organ Transplant Act of 1984 that remove financial barriers to living organ donation. We believe that reimbursing for lost wages and child/elder care in the context of living donation brings the U.S. in line with more than a dozen other countries that have been doing this for many years.

We share the following comments regarding this proposal:

- We believe that it is misguided to frame this proposed rule and regulatory amendment in such a way as to suggest that it is likely to increase living donor transplants (e.g., The agency further believes that this regulatory language, if finalized as proposed, will encourage and allow for more potential living organ donors to proceed to donation.”). While we all want to believe that this will occur, there is no evidence currently to support this supposition. Several trials, including a current NIH-funded trial on donor lost wages, failed to show an increase in living donation when making lost wages reimbursement available to potential living kidney donors.
- While we are firmly supportive of offering this reimbursement of expenses because it is the right thing to do, as it should not cost a living donor to donate, we are concerned that framing the change as a way to increase living donor transplants may lead to a repeal of this funding if it does not yield the intended results.
- We applaud this effort to remove financial disincentives to living donation but offer that it does not go far enough. Hays et al¹ and the 2016 donor cost data² published in the American Journal of Transplantation reflect that there are other donation-related costs not currently captured by NLDAC and not included with this proposed rule change. Examples of the costs that we recommend for your consideration include co-pays and deductibles for medical visits and drug costs related to donation that are not otherwise covered by the recipient’s insurance (for both evaluation and post-donation follow-up); and the cost of the medical evaluation to determine if a new-onset medical issue is related to donation.
- As written, it is not clear what is included as “lost wages.” For example, does use of

¹ R. Hays, J. R. Rodrigue, D. Cohen, G. Danovitch, A. Matas, J. Schold and D. LaPointe Rudow, Financial Neutrality for Living Organ Donors: Reasoning, Rationale, Definitions, and Implementation Strategies, *American Journal of Transplantation* 2016 Jul;16(7):1973-81. doi: 10.1111/ajt.13813. Epub 2016 May 9.

² J.R. Rodrigue, JD Schold, P. Morrissey, J. Whiting, J. Vella, L.K. Kayler, D. Katz, J. Jones, B. Kaplan, A. Fleishman, M. Pavlakis, D.A. Mandelbrot, KDCOP Study Group, Direct and Indirect Costs Following Living Kidney Donation: Findings from the KDOC Study, *American Journal of Transplantation* 2016 Mar;16(3):869-76. doi: 10.1111/ajt.13591. Epub 2016 Feb 4.

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medical leave or vacation time count against any claim on lost wages? This would be a financial benefit no longer available to the living donor due to donation. Table 3 in the KDOC article² reflects that the loss of paid sick and/or vacation time to an employee have substantial costs when factored in. It does not appear that this is considered in the proposed rule change, though we do acknowledge the call for comment on page 70142 on “foregone medical insurance benefits.” We ask that these benefits outside of actual lost wage for missed work are also included

- It is noted that future rule change proposals will address an increase in the income eligibility requirements for reimbursement via NLDAC. While this possible increase in NLDAC is an excellent step, it must be acknowledged that does not address the fundamental conceptual problem with NLDAC- that it has helped fewer than 8% of all living donors since its inception.

Specifically, reimbursement eligibility is means tested, which includes consideration of the recipient’s household income. The proposed rule change appears to maintain this requirement. The AST believes that this is misguided and will severely limit access to lost wage reimbursement and most certainly will not likely lead to increases in living donation. As noted within the rule proposal itself, the recipient’s annual household income – on average – is lower than that of donors. Less than 10% of living donors receive any type of financial assistance from their recipient², 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 donor; and (b) why continue with this eligibility criterion when we have sufficient evidence that it is a deterrent to donors even applying for NLDAC assistance. The AST strongly favors removal of the recipient’s household income from the NLDAC eligibility criteria altogether, as it should not provide the basis for determining whether living donors are eligible for reimbursement.

- It is unclear if the total reimbursement cap per living donor will increase. While there appears to be discussion regarding how this may need to happen, it is unclear how this will be made actionable and who has the authority to authorize the change. We have similar questions regarding the potential cap on lost wages reimbursement. It is unclear who will make this determination- HRSA, NLDAC, ACOT?

Despite these concerns and limitations, the AST sees these proposed changes as a very positive step in the right direction.