



February 18, 2020

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Thomas J. Engels
Administrator
Health Resources and Services
Administration
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

Re: HHS Docket No. HRSA–2019–0001: Removing Financial Disincentives to Living Organ Donation

Dear Secretary Azar and Administrator Engels:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed rule for Removing Financial Disincentives to Living Organ Donation. ASN's more than 22,000 members are leading the fight to prevent, treat, and cure kidney diseases and advocating for the highest quality care for the 37,000,000 Americans and more than 850,000,000 people worldwide affected by kidney disease. In keeping with ASN's mission, we applaud the Trump Administration for creating an ambitious agenda for kidney health through the Executive Order on Advancing American Kidney Health, aspects of which are addressed in this proposed rule. ASN strongly supports these goals and stands ready to work in collaboration with the administration, Congress, and other stakeholders to achieve success.

The President's Executive Order emphasized that supporting living organ donors can help address the current demand for kidney transplants. ASN agrees and supports the proposed rule to expand the scope of reimbursable expenses for living donors to include lost wages, childcare, and eldercare expenses for those donors who lack other forms of financial support. Under certain conditions, these expenses may be covered by the National Living Donor Assistance Center (NLDAC), which exists to provide access to transplantation for those who want to donate but face financial barriers to doing so.

ASN believes that this proposal could increase the number of transplant recipients receiving a better-quality organ in a shorter time period from living donors. In general, recipients of kidney transplants from living organ donors have better clinical outcomes than those who continue dialysis or those who receive a deceased donor kidney transplant.

ASN recommends some refinement of the proposed rule as follows:

- Modifying the language to be more inclusive. In several places, the proposal language implies that the focus is primarily towards familial donors (or close associations) and ASN encourages HRSA to expand that language.

For example, in *Sec. III. Discussion of Proposed Rule* says “...the Agency believes that there are many potential living organ donors who would like to donate an organ to a family member or friend...” In the *Summary of Impacts*, the agency writes “Therefore, a hypothetical 20 percent increase in the rate of LDKT in model markets in a single year, representing about 500 new kidney transplants mainly from relatives of recipients...”¹

While related living donors are the largest donor group, there has been a notable decline over the last decade, while unrelated donations have steadily increased – this includes directed donors who may give to a specific recipient when they learn of a need (sometimes without any preexisting relationship – e.g. through social media or other means) and a growing number of non-directed donors (previously called ‘altruistic’) who donate to a list without a directed recipient. Such donors should also have access to the full spectrum of NLDAC resources across all phases of donation, including the initial evaluation. Barriers to starting the evaluation can prevent a healthy, otherwise willing, individual from ever becoming a living donor.

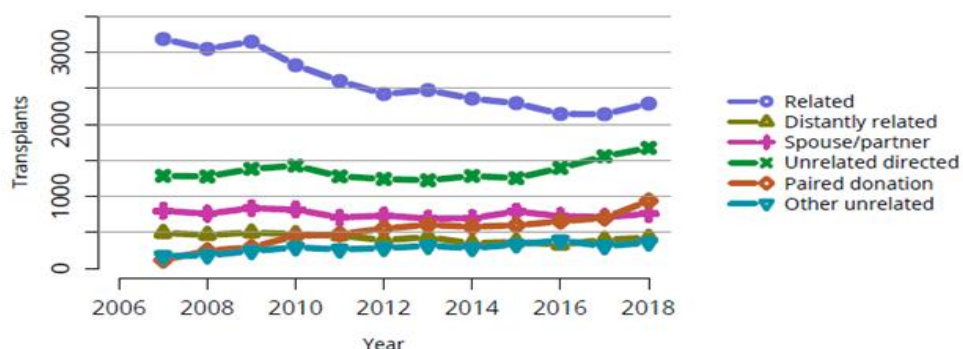


Figure KI 56. Kidney transplants from living donors by donor relation. As reported on the OPTN Living Donor Registration Form.

2

- Liberalizing recipient income cap for donor eligibility

Eligibility for NLDAC assistance is determined by the recipient’s household income. The recipient’s yearly household income should not be more than 300% of the current

¹ <https://www.hhs.gov/sites/default/files/living-donor-nprm.pdf>

² Hart A, Smith JM, Skeans MA, et al. OPTN/SRTR 2018 Annual Data Report: Kidney. Am J Transpl 2020;20 Suppl s1:20-130.

Federal Poverty Guidelines, which is currently \$38,280 for one individual, otherwise waivers are required.

While the recipient income cap is not dealt with directly in this proposed rule, ASN believes that the current income cap is too low and leaves many potential donor candidates excluded from support. In addition, while the National Organ Transplant Act (NOTA) permits recipients to support costs incurred by donors, the means testing of recipients in the NLDAC program assumes: 1) that a recipient is identified; 2) a donor-recipient relationship with sufficient comfort that the donor can reasonably ask the recipient for financial support, which includes disclosing to the recipient that the individual is pursuing donor candidate evaluation.

Donor-recipient relationships have evolved substantially over the last 15 years. Unrelated donors are the fastest growing group, and more donor candidates are stepping forward without established relationships with a recipient and may wish to begin an evaluation confidentially. The relationship with the recipient in these cases can be very different than donation to a family member, thus, requiring the donor to ask a recipient for financial support during the evaluation phase requires the donor to disclose that they are pursuing the evaluation, denies them the right to be evaluated confidentially, and may create expectations from the receipt that challenge autonomous decision-making – thus posing barrier to, rather than supporting, starting the evaluation process.

In other words, the current foundation of requiring support from the intended recipient for coverage of travel and incidental non-medical expenses before accessing NLDAC as “payer of last resort” can deter the autonomous decision of otherwise willing individuals to privately pursue an evaluation in a way that is likely difficult to measure.

- Removing barriers for non-directed donors

Although non-directed donors may apply to NLDAC once a recipient is identified, this delay in the application process creates a barrier for initiation of an evaluation, as non-directed donors do not have an intended recipient at the evaluation stage. Non-directed donors are an extremely impactful group because they often participate in paired donation exchanges that produce a series of transplants from their gift. Non-directed donors should have access to NLDAC support across all phases of care.

With the significant need for organs and the trends in living donation illustrated in the figure above, ASN urges HRSA to modify the proposed rule to remove these barriers. With 115,000 Americans waiting for an organ, the time has come to remove barriers to NLDAC access for all potential donors, regardless of their relationship to the intended recipient, and support opportunities for all who hope to give the gift of life, including providing assistance to help cover their expenses, when appropriate.

Thank you for the opportunity to make these comments. If you would like to discuss these comments further, please contact David White, ASN Regulatory and Quality Officer, at (202) 640-4635 or dwhite@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'A. Agarwal', with a long horizontal stroke extending to the right.

Anupam Agarwal, MD, FASN
President