

# PROPOSED NLDAC AMENDMENTS

4.19.19

## RATIONALE

Reimbursing the expenses of living organ donation has long been a consensus goal of the transplant community<sup>1</sup> with support from groups like the American Society of Nephrology, American Society of Transplantation, the National Kidney Foundation, and Waitlist Zero.

The National Living Donor Assistance Center is authorized by statute to provide grants to reimburse donor expenses. A recent study found that for every dollar spent on NLDAC's travel reimbursement program, Medicare saves \$28 in dialysis costs due to the increase in transplantation.<sup>2</sup> Expanding NLDAC through regulation to cover lost wages and other expenses like childcare and caretaker expenses could dramatically expand the impact of the program without requiring new authorizing legislation.

Based on previous studies of donor expenses and the impact of donor benefit policies, the expected per-donor cost of such a program would be roughly \$4,000-\$4,900<sup>3</sup> and could realistically be expected to increase living donation rates by 15%-30% (see Evidence of Impact below). With a base rate of 6,000 donors in the status quo, that implies an increase of between 900 and 1,800 additional transplants each year for a total annual cost of \$27.6M-\$37.4M and net savings of \$97M-\$223M.<sup>4</sup>

**Evidence of Impact:** Significant evidence exists that expanding reimbursement would increase donation:

### **1. Similar Reimbursement Measures Have Increased Donation**

- a. After Israel began reimbursing donor lost wages and providing other benefits, living donation doubled;<sup>5</sup>

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<sup>1</sup> See e.g., Rudow DP, Hayes R, Baliga P, et al. Consensus Conference on Best Practices in Live Kidney Donation: Recommendations to Optimize Education, Access, and Care. *Am J Transplant.* 2015 Apr; 15(4): 914-922. Salomon DR, Langnas AN, Reed AI et al. AST/ASTS workshop on increasing organ donation in the United States: creating an "arc of change" from removing disincentives to testing incentives. *Am J Transplant.* 2015 May;15(5):1173-9. An Open Letter to HHS Secretary Burwell on Ethically Increasing Organ Donation. *Transplantation.* February 2015 - Volume 1 - Issue 1 - p 1-19. Gaston R.S. Danovitch G.M., Epstein R.A. et al. Limiting Financial Disincentives in Live Organ Donation: A Rational Solution to the Kidney Shortage. *Am J. Transplant* 2006; 6: 2548-2555.

<sup>2</sup> 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.

<sup>3</sup> See e.g. Rodrigue, J.R. Schold JD, Morrissey P. et al. Predonation Direct and Indirect costs Incurred by Adults Who Donated a Kidney: Findings from the KDOC Study. *Am J Transplant.* 2015 Sep;15(9):2387-93. Rodrigue, J.R. Schold JD, Morrissey P. et al., Direct and Indirect Costs Following Living Kidney Donation: Findings From the KDOC Study. *Am J. Transplant* 2016 Feb; 16: 869-876; Klarenbach S, Gill JS, Knoll G, et al. Economic Consequences Incurred by Living Kidney Donors: A Canadian Multi-Center Prospective Study. *Am J Transplant.* 2014 Apr; 14(4): 916-922; and Warren P, Gifford K, Hong B et al. Development of the National Living Donor Assistance Center: reducing financial disincentives to living organ donation. *Prog Transplant.* 2014 Mar; 24(1): 76-81.

<sup>4</sup> Based on an estimated savings of \$145,000 per transplant. Held PJ, McCormick F, Ojo A et al. A Cost-Benefit Analysis of Government Compensation of Kidney Donors. *Am J Transplant.* 2016 Mar;16(3):877-85.

<sup>5</sup> Lavee, J. Ashkenazi T., Stoler A et al. Preliminary marked increase in the national organ donation rate in Israel following implementation of a new organ transplantation law. *Am J. Transplant* 2013: Mar;13(3):780-5.

- b. A 2017 study of NLDAC travel reimbursement found a 14% increase in transplant at participating centers.<sup>6</sup>
  - c. A 2015 study of state tax deductions for donor reimbursement found a 52% increase in donation to non-family members;<sup>7</sup> and
  - d. In a survey of NLDAC donors, 75% said they would not have donated without reimbursement.<sup>8</sup>
2. **Donor Income Significantly Affects Transplant Rates**
- a. Donation varies directly by income level<sup>9</sup> – raising the average rate of donation to that of the top income quintile would increase donation by 35%; and
  - b. Donation rates for the lowest three income quintiles declined after the last recession;<sup>10</sup>

### SUMMARY OF CHANGES

- **Qualifying Expenses:** The expenses eligible for reimbursement by NLDAC are expanded to include all expenses incurred as a result of donation, including but not limited to “lost income (including demonstrated lost non-employment income); the economic value of limited sick or vacation days expended by the donor, childcare, eldercare, medications, care associated with the donor surgery, travel, lodging, meals and incidental expenses incurred by the donor and/or his/her accompanying person(s).” Instructions are provided for calculating lost income, childcare, and eldercare expenses.
- **Income Eligibility:** The recipient income eligibility cutoff is raised from 300% of the poverty line to 600% of the poverty line.
- **Non-Directed Donors:** Donors without a designated recipient would be deemed eligible for the program regardless of the income of their actual direct recipient.
- **Donor Residence Requirement:** Donors would not need to be U.S. residents or citizens to participate in the program.

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<sup>6</sup> Schnier K, Merion R, Turgeon N, et al. Subsidizing altruism in living kidney donation. *Economic Inquiry* 2018; Jan;56(1):398-423.

<sup>7</sup> Bilgel, F and Galle, B, Financial incentives for kidney donation: A comparative case study using synthetic controls. 43 *J. Health Econ* 103 (2015). *But see* Boulware LE, Troll MU, Platinga LC, Powe NR. The association of state and national legislation with living kidney donation rates in the united states; a national study. *Am J Transplant* 2008; 8: 1451–1470, which finds no evidence of impact for state tax deductions.

<sup>8</sup> See Warren, 2014 *supra*.

<sup>9</sup> Gill J, Dong J., Rose C. et al. The Effect of Race and Income on Living Kidney Donation in the United States. [J Am Soc Nephrol](#). 2013 Nov; 24(11): 1872–1879. See also Gill J, Dong J., and 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

<sup>10</sup> Gill J, Dong J, and Gill J. Population Income and Longitudinal Trends in Living Kidney Donation in the United States *J Am Soc Nephrol*. 2015 Jan; 26(1): 201–207.

## AMENDED REGULATORY TEXT

### National Living Donor Assistance Center (NLDAC) Program Eligibility Guidelines as Amended

Section 3 of the Organ Donation and Recovery Improvement Act (ODRIA), 42 U.S.C. 274f, establishes the authority and legislative parameters to provide reimbursement for travel and subsistence expenses incurred towards living organ donation. HRSA awarded a cooperative agreement to the Regents of the University of Michigan (Michigan), which partnered with the American Society of Transplant Surgeons (ASTS), to establish the National Living Donor Assistance Center (NLDAC) to operate this Program.

As provided for in the statutory authorization, this Program is intended to provide reimbursement only in those circumstances when payment ~~is unlikely to~~ be covered by other sources of reimbursement. The NLDAC, under Federal law, cannot provide reimbursement to any living organ donor for travel and other qualifying expenses if the donor can ~~reasonably expect to~~ receive reimbursement for these expenses from any of the following sources:

- (1) any State compensation program, an insurance policy, or any Federal or State health benefits program;
- (2) an entity that provides health services on a prepaid basis; or
- (3) the recipient of the organ.

In ~~previous rounds of public comment concerning this regulation, the majority of comments maintained that no threshold of income eligibility for the recipient of the organ should exist. In response,~~ a threshold of income eligibility for the recipient of the organ is ~~600~~ percent of the Department of Health and Human Services (HHS) Poverty Guidelines in effect at the time of the eligibility determination. The Program assumes that recipients whose income exceeds this level will have the ability to reimburse the living organ donor for the ~~qualifying expenses authorized by the Secretary of HHS.~~ The Program provides an exception to this rule for financial hardships. A transplant social worker, or appropriate transplant center representative, based on a complete recipient evaluation, can provide an official statement, notwithstanding the recipient's income level, that the recipient of the organ would face significant financial hardship if required to pay for the qualifying living organ donor expenses. A recipient's financial hardship is defined as circumstances in which the recipient's income exceeds ~~600~~ percent of the HHS Poverty Guidelines in effect at the time of the eligibility determination, but the individual will have difficulty paying the donor's expenses due to other significant expenses. Whether or not hardship exists in a particular case requires a fact-specific analysis; examples of significant expenses include circumstances such as paying for medical expenses not covered by insurance or providing significant financial support for a family member not living in the household (e.g., elderly parent). Waiver requests by the transplant center, on behalf of the ~~recipient,~~ shall be made in writing and shall clearly describe the circumstances for the waiver request. The NLDAC will review waiver requests and make a recommendation to HRSA to either approve or deny the request. HRSA will make the final determination and communicate its final determination to the

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All persons who wish to become living organ donors are eligible to receive reimbursement for their qualified expenses if they cannot receive reimbursement from the sources outlined above and if all the requirements outlined in the *Criteria for Donor Reimbursement Section* are satisfied. However, because of the limited funds available, prospective living donors who are most likely not able to cover these expenses will receive priority.

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The ability to cover these expenses is determined based on an evaluation of (1) the donor and recipient's income, in relation to the HHS Poverty Guidelines (described in Table 1.1 below), and (2) financial hardship. As a general matter, income refers to the donor or recipient's total household income. A donor may be able to demonstrate financial hardship, even if the donor's income exceeds [600](#) percent of the HHS Poverty Guidelines, if the donor will have difficulty paying the qualifying expenses due to other significant expenses. Although all requests will be reviewed on a case-by-case basis, examples of significant expenses include circumstances such as providing significant financial support for a family member not living in the household (e.g., elderly parent). Waiver requests by the transplant center, on behalf of the donor, shall be made in writing and shall clearly describe the circumstances for the waiver request. The NLDAC will review waiver requests and make a recommendation to HRSA to either approve or deny the request. HRSA will make the final determination and communicate its final determination to the NLDAC. The [NLDAC](#) will notify the transplant center of the final determination. HRSA's determination will not be subject to appeal.

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Donors will be given preference in the following order of priority:

*Preference Category 1:* The donor's income and the recipient's income are each [600](#) percent or less of HHS Poverty Guidelines in effect at the time of the eligibility determination in their respective states of primary residence.

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*Preference Category 2:* Although the donor's income exceeds [600](#) percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination, the donor demonstrates financial hardship. The recipient's income is at or below [600](#) percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination.

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*Preference Category 3:* Any living organ donor, regardless of income or financial hardship, if the recipient's income is at or below [600](#) percent of the HHS Poverty Guidelines in effect in the recipient's State of primary residence at the time of the eligibility determination.

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*Preference Category 4:* Any living organ donor, regardless of income or financial hardship, if the recipient (with income above [600](#) percent of the HHS Poverty Guidelines in effect in the State of primary residence at the time of the eligibility determination) demonstrates financial hardship.

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HRSA reserves the right for the grantee to prioritize those most in financial need (based on income or other specified factors) if it receives large numbers of applications concerning donors meeting preference category 1.

The HHS Poverty Guidelines for 2009 (**Federal Register**, Vol. [84](#), No. [22](#), February 1, 2019, pp. [1167-1168](#)) are shown in the table below.

Persons in family or household	48 Contiguous States and DC	Alaska	Hawaii
1	\$12,490	\$15,600	\$14,380
2	16,910	21,130	19,460
3	21,330	26,660	24,540
4	25,750	32,190	29,620
5	30,170	37,720	34,700
6	34,590	43,250	39,780
7	39,010	48,780	44,860
8	43,430	54,310	49,940
For each additional person, add	4,420	5,530	5,080

These guidelines are updated periodically.

### Criteria for Donor Reimbursement

- Any individual who in good faith incurs qualifying expenses toward the intended donation of an organ.
- The recipient of the organ is a U.S. citizen or lawfully admitted resident of the U.S.
- The recipient has primary residence in the U.S. or its territories.
- For the purpose of reimbursement toward travel expenses, travel is originating from the donor's primary residence.
- Donor and recipient certify that they understand and are in compliance with Section 301 of NOTA (42 U.S.C. 274e) which states in part " \* \* \* It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for

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valuable consideration for use in human transplantation if the transfer affects interstate commerce.”

6. The transplant center where the donation procedure occurs certifies to its status of good standing with the Organ Procurement and Transplantation Network (OPTN).

### Qualifying Expenses

For the purposes of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, *qualifying expenses* refers to all reasonable expenses incurred in the act of donating an organ, which include but are not limited to lost income (including demonstrated lost non-employment income); the economic value of limited sick or vacation days expended by the donor, childcare, eldercare, medications, care associated with the donor surgery, travel, lodging, meals and incidental expenses incurred by the donor and/or his/her accompanying person(s) as part of:

(1) Donor evaluation and/or

(2) Hospitalization for the living donor surgical procedure,

~~(3) The 4-8 weeks of recovery following surgery; and/or~~

~~(4) Medical or surgical follow-up, clinic visits, or hospitalization within 5 calendar years following the living donation procedure connected to donation (or beyond the 5-year period if exceptional circumstances exist).~~

~~With regards to travel, the~~ Program will pay for a total of up to five trips; three for the donor and two for accompanying persons. However, in cases in which the transplant center requests the donor to return to the transplant center for additional visits as a result of donor complications or other health related issues, NLDAC shall provide reimbursement for the additional visit(s) for the donor and an accompanying person. The accompanying persons need not be the same in each trip.

The total Federal reimbursement for qualified expenses during the donation process for the donor and accompanying individuals shall not exceed \$14,000.00. Reimbursement for qualifying travel expenses shall be provided at the Federal per-diem rate, except for hotel accommodation, which shall be reimbursed at no more than 150 percent of the Federal per diem rate.

~~For kidney donors who experience lost income, the calculation of such income shall be derived from an average of all income received for a three-month period sampled by the eligibility questionnaire with such period not to exceed twelve months before the actual donation. The total period of time related to lost wages or expended sick or vacation days shall not exceed four weeks for donors whose employment does not require physical labor unless special circumstances are demonstrated. The total period of time related to lost wages or expended sick or vacation days shall not exceed ten weeks for donors whose employment does require physical labor unless special circumstances are demonstrated.~~

~~Whether or not special circumstance exist in a particular case requiring extension of the reimbursement window requires a fact-specific analysis. Waiver requests by the transplant center, on behalf of the recipient, shall be made in writing and shall clearly describe the circumstances for the waiver request. The NLDAC will review waiver~~

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requests and make a recommendation to HRSA to either approve or deny the request. HRSA will make the final determination and communicate its final determination to the NLDAC. The NLDAC will notify the transplant center of the final determination. HRSA's determination will not be subject to appeal.

For eldercare or childcare expenses that constitute qualifying expenses, the rate for reimbursement shall not exceed 150% the prevailing local cost of such services in the donors' residence.

Qualifying expenses shall be reimbursed as close in time as possible to their being incurred by the donor, including by pre-payment where practicable.

For donor and recipient pairs participating in a paired exchange program, the applicable eligibility criteria for the originally intended recipient shall be considered for the purpose of reimbursement of qualifying donor expenses even though the final recipient of the donated organ may not be the recipient identified in the original donor-recipient pair.

Given the utilization of non-directed donors in transplant chains of multiple recipients, one or more of whom are very likely to fall within the income threshold and given that it is unreasonable to expect a recipient to cover such donors' expenses where no recipient has yet been identified, donors without a designated recipient otherwise entitled to reimbursement under this program will be deemed eligible notwithstanding the income of their actual, direct recipient. Donors participating in an advanced donation program (a.k.a. a "kidney voucher") program shall be deemed to be non-directed donors.

### Maximum Number of Prospective Donors per Recipient

- *Kidney*: two donors at a time with a maximum of five donors
- *Liver*: two donors at a time with a maximum of five donors
- *Lung*: two donors at a time with a maximum of six donors

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### Special Provisions

Many factors may prevent the intended and willing donor from proceeding with the donation. Circumstances that would prevent the transplant or donation from proceeding include: Present health status of the intended donor or recipient, perceived long-term risks to the intended donor, justified circumstances such as acts of God (e.g., major storms or hurricanes), or a circumstance when an intended donor proceeds toward donation in good faith, subject to a case-by-case evaluation by the NLDAC, but then elects not to pursue donation. In such cases, the intended donor and accompanying persons may receive reimbursement for qualified expenses incurred as if the donation had been completed. Under Program policy, a form will be filed with the Internal Revenue Service (IRS) reporting funds disbursed as income for expenses not incurred.