



THE LIVING ORGAN VOLUNTEER ENGAGEMENT (LOVE) ACT

The Issue: There are approximately 93,000 Americans waiting for a kidney transplant, with tens of thousands more in need of a transplant not on the waiting list. The average wait is 3-5 years, and 12-17 persons die each day waiting for a kidney transplant. The waiting list is growing faster than transplantable kidneys are becoming available. While more needs to be done to improve kidney recovery from deceased donors, the shortfall in life-saving kidneys only can be closed if living donation increases.[1] Living donation is safe, ethical, and has been successful for decades. Yet, while deceased donation has more than doubled in ten years, the number of live kidney donations has not increased in twenty years, leaving tens of thousands on dialysis, and costing the Medicare program billions of dollars.[2]

There are three specific policies that can be adopted to increase living donation:

- (1)** Create kidney donation patient navigators, to assist ESRD patients in identifying donors and to assist prospective donors in navigating and completing the transplant process;
- (2)** Cost reimbursement, to eliminate the financial barrier to living donors wishing to donate;
- (3)** National education, to inform the country on the opportunity to donate. Because Medicare bears the costs of treating ESRD patients while they await transplants, and because Medicare already pays for navigators and certain living donor costs, the legislation clarifies the Medicare statute to address these issues.

THE LEGISLATION – SECTION BY SECTION

The LOVE Act will amend the Medicare statute as follows:

Section 1 – Short Title:

The legislation is called the LOVE Act.

Section 2 – Patient Navigators:

Building on the existing Medicare coverage and reimbursement for “Principal Illness Navigators”[3] (PINs), the legislation would create a new, separately reimbursable, class of “living kidney donor navigators” to assist ESRD patients in identifying a donor, and to assist donors in getting through the screening and donation process. The legislation, modeled on existing navigator programs around the United States,[4] defines who can serve as a navigator (based upon the existing Medicare PIN coverage criteria), the classes of potential transplant recipients and donors that navigators are to work with, and the different types of services that navigators can provide (again, modeled on existing Medicare PIN criteria). The legislation also establishes that kidney donation navigators can be paid by billing through a supervising physician who can be a nephrologist, transplant physician, or other physician, and establishes unique billing codes and payment rates for these services. Importantly, the legislation waives co-payment requirements for navigators (in the same way the Medicare law does for other services provided to living donors). Reimbursement is higher than for regular PIN navigators, given the significant savings that living donation contributes to the Medicare program. Finally, the legislation limits one navigator to a recipient and donor at a time, although separate navigators can concurrently serve a recipient and a donor.

Section 3 – Cost Reimbursement:

The Medicare statute, Section 1881(d), already provides that Medicare should cover all “reasonable expenses” of a donor related to the donation. For historical reasons, CMS has limited such coverage to the Part A/B costs of the transplant, and does not cover other reasonable out-of-pocket expenses incurred by the living donor related to the transplant.[5]

To correct this anomaly, the legislation would clarify that “reasonable expenses,” to the extent not already reimbursed by any other person or program (including the National Living Donor Assistance Center) are to include (1) direct costs, including all medical care and diagnostic testing necessary for a donation not already covered under this subsection, including costs before, during, and after the donation, and any follow-up care for the actual period of recovery following the donation (including 6-month, 1-year and 2-year follow-up visits) and any other visits if such medical care before or after the date of the donation is directly related to the donation or any effects of the donation on the donor; (2) indirect costs, including lost wages of up to \$2,500 per week for up to 8 weeks, travel (up to \$5,000), dependent-care and other caregiver expenses, and other related expenses as determined reasonable by the Secretary without regard to the financial capacity of the donor or recipient; and (3) comprehensive life and disability insurance of up to \$1 million of coverage (indexed for inflation) for any loss, health care expense, or disability directly related to the donation or donation process.

Section 4 – Education:

Modeled on the existing National Marrow Donor Program (NMDP) educational efforts, the legislation authorizes HRSA to undertake a national educational effort. Data indicates that 85% of Americans would consider living donation, but were more positively inclined to donate after exposure to information about donation.[6]

Section 5 – Coordination:

There is no national database of available kidney donors in the United States. The legislation would instruct HHS to establish a national list of potential living kidney donors, similar to the NMDP database of bone marrow donors.

[1] Matas AJ, Montgomery RA, Schold JD. The Organ Shortage Continues to Be a Crisis for Patients With End-stage Kidney Disease. *JAMA Surg.* 2023 Aug 1;158(8):787-788. doi: 10.1001/jamasurg.2023.0526. PMID: 37223921 (“Given that only about 1% of deaths occur in a manner suitable for organ donation, there appears to be no possibility that any further increase in deceased donation will be sufficient to eliminate the shortage. Similarly, there is currently a considerable emphasis on minimizing the number of deceased donor kidneys recovered but not transplanted; however, at best, that alone might result in approximately 2000 more transplants per year, a mere dent in the problem.”)

[2] Brannon, I., Saving Lives While Saving Money, *Regulation*, Summer 2023 (“Dialysis is costly. Medicare spends nearly \$100,000 per year for each dialysis patient it covers. It spent over \$130 billion treating kidney disease in 2022. Private insurers also paid billions of dollars to cover the costs of dialysis for their enrollees. Patients with end-stage kidney disease constitute less than 1 percent of the Medicare population but account for 7 percent of the Medicare budget.”)

[3] 88 Fed. Reg. 78818, 78937-48 (Nov. 16, 2023).

[4] Locke, J., et al. Enhanced Advocacy and Health Systems Training through Patient Navigation Increases Access to Living Donor Kidney Transplantation, *Transplantation*. 2020 Jan; 104(1): 122-129. doi: 10.1097/TP.0000000000002732 (describing University of Alabama Birmingham kidney donor navigator program, and finding that “[i]mplementation of an LDN Program was associated with a 9-fold increased likelihood of living donor screenings and a 7-fold increased likelihood of having an approved living kidney donor among program participants compared to standard of care); Garonzik-Wang JM, Berger JC, Ros RL, Kucirka LM, Deshpande NA, Boyarsky BJ, Montgomery RA, Hall EC, James NT, Segev DL. Live donor champion: finding live kidney donors by separating the advocate from the patient. *Transplantation*. 2012 Jun 15;93(11):1147-50. doi: 10.1097/TP.0b013e31824e75a5. PMID: 22461037; PMCID: PMC3374007 (describing Johns Hopkins kidney recipient “Champions” program, and finding that introducing a navigator resulted in a “dramatic proportion of participants (almost 50%) [which] identified live donors” compared to a control group.

[5] See, e.g. Medicare Provider Reimbursement Manual, Part 1, Chapter 31, Section 3106 (rejecting coverage of travel expenses). Medicare does not even address coverage of child care costs or lost wages.

[6] Kaplow K, Ruck J., Levan M, Thomas A, Stewart D, Massie A, Sung H, Pisano S, Sidoti, C, Segev D, Sinacore J, Waterman A; National Attitudes Toward Living Kidney Donation in the United States: Results of a Public Opinion Survey; *Kidney Med.* Vol. XXX (prepublication); 16 Jan. 2024; doi: 10.1016/j.xkme.2023.100788 (“In this national survey assessing public opinions on living kidney donation, we found that 694 (86.6%) respondents would consider donating a kidney while still living. Those who were more willing to donate had recent exposure to content about living kidney donation...”).