Utilizing Executive Action to Establish Transplant Center Based Living Donor Facilitator Programs

The LOVE Act (H.R. 7581) would expand Medicare coverage for living donor facilitator training through legislation. These goals can also be advanced through executive action using existing Medicare authorities. The central tenet of the bill is the inclusion of coverage under Organ Acquisition Costs (OAC) for living donor facilitator trainers employed by transplant hospitals. These trainers will work with family members, friends, or co-workers of the recipient to assist them in both identifying a potential living donor and then supporting that donor successfully through the full transplantation process. Multiple studies have shown that with appropriate training, these volunteer facilitators can dramatically increase the percentage of recipients who successfully identify a living donor and help that donor complete their evaluation and reach the operating room for living kidney donation. Currently, transplant hospitals must rely on non-Medicare funding sources to employ these trainers. Instead, they can be included as a direct pre-transplant reimbursable cost under the established OAC guidelines.

The need for action is urgent. In 2025, deceased donor recovery decreased with a corresponding decrease in deceased donor kidney transplants, leading to fewer total kidney transplants.[1] A focus on increasing living donor kidney transplants can immediately fill this void along with saving Medicare an estimated $6.6 billion over 10 years with an estimated doubling of annual living donor transplants.[2] [3]

OAC Framework: The language governing OAC outlines "allowable" Medicare Part A services along with "reasonable" cost reimbursements provided "prior" to transplantation. Numerous OAC references stipulate "reimbursement based on a reasonable cost" in the OAC regulations serving to disincentivize fraud and abuse as the submitted costs are subject to review by the OIG.[4] Reimbursement by Medicare is cost-based and emphasis is placed on ensuring that all appropriate cost accounting practices are followed. The Medicare cost report for transplant centers includes both direct costs such as salaries and space and indirect costs. Fraud and abuse are minimized by including appropriate documentation.

Amending OAC Via Executive Action: The most recent example of executive action resulting in modification of the OAC followed President Trump's Executive Order on Advancing American Kidney Health in 2019. This resulted in a final rule issued by CMS on November 20, 2020, updating the Conditions for Coverage for the Organ Procurement Organizations (OPO) that provide deceased donor organs to transplant hospitals with reimbursement under the OAC.[5] In addition, the Increasing Organ Transplant Access (IOTA) model can be reformed to include this transplant facilitator trainer function under its mandatory transplant center focused value-based care model[6], enabling all selected transplant hospitals to employ such trainers for volunteer facilitators. This would lead to a significant increase in living donor transplants performed by these centers with a corresponding increase in positive performance payments.

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[1] hrsa.unos.org/data/view-data-reports/national-data/
[2] kidneytransplantcollaborative.com/wp-content/uploads/CONGRESSIONAL-BRIEFING.pdf
[3] The Moran Company, The Living Organ Volunteer Engagement (LOVE) Act: Fiscal Implications (March 15, 2024), available from author.
[4] www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-413/subpart-L
[5] https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to
[6] www.cms.gov/priorities/innovation/innovation-models/iota

OACs and Living Kidney Donor Facilitation: OACs serve to encourage and incentivize hospitals to provide transplant services. Shortly after Congress amended the Social Security Act to include Medicare coverage for end-stage renal disease in 1972, kidney acquisition cost centers were created so that hospitals could receive compensation for reasonable expenses related to the procurement of deceased donor kidneys. One of the earliest examples of Medicare extending the scope of OACs was to include reasonable expenses for extra-renal organs allowing for hospitals to establish organ-specific OACs.

Updating the OAC to provide coverage for living kidney donor facilitator trainers employed by transplant hospitals has the potential to address the current crisis in kidney care: There are simply not enough available kidneys to meet the demand posed by the ever-growing waitlist for kidney transplants—now over 94,000 people long. Increasing living kidney donor transplants can immediately fill this void. Given that OAC policies have been updated through executive action on multiple occasions, including most recently following the 2019 Executive Order on Advancing American Kidney Health, extending OAC coverage to include facilitator training costs represents a well-precedented use of existing administrative authority.

Overwhelming evidence demonstrates that CMS can significantly increase the number of living kidney transplants if volunteer facilitators help donors and recipients through the complex processes of donation and transplant.

The University of Alabama at Birmingham used trained facilitators to work with living donors and demonstrated a 7-fold increase in successful completion of the full evaluation.[7] At the University of Alabama Birmingham, the transplant hospital trained facilitators in an 8-week advocacy and educational course, instructing the facilitators on engaging and educating the family, friends and social network of the prospective recipient about the prospects of living donation. Following the "advocacy" training, the facilitator worked with the recipients' networks to identify living donors. Following the training, facilitators applied their knowledge to guide living donors through the medical testing process and through the transplant surgery. In addition to the advocacy training, the facilitator also received "systems training" on the "how, why and when" of the medical testing journey, which they put to work in regular contact with the prospective donor, including before each medical visit, to ensure the living donor made it through the process.

Similarly, at Johns Hopkins University, the Champions program demonstrated that with appropriate training, these volunteer facilitators could increase the likelihood of the recipient finding a living donor from 0% to 50%.[8] The training was focused on giving facilitators the skills to seek out the living donor. By providing intensive training in transplant, how to initiate the discussion with living donors, building the networks, and sharing success stories, the facilitators not only were able to directly identify living donors for recipients, but the recipients also grew more comfortable participating in the process.

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[7] pmc.ncbi.nlm.nih.gov/articles/PMC6773517/

[8] 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.