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VIA E-Mail

www.regulations.gov

Elizabeth Fowler, Ph. D., J.D.,
Deputy Administrator and Director
of the Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5535-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model, 89 Fed. Reg. 43518 (May 17, 2024)

Dear Dr. Fowler:

On behalf of the Kidney Transplant Collaborative (KTC), we are pleased to offer comments on the Increasing Organ Transplant Access (IOTA) Model, CMS-5535-P, RIN 0938 AU51, recently published in the Federal Register (the "Proposal" or the "Model"). 89 Fed. Reg. 43518 (May 17, 2024). We applaud the Center for Medicare and Medicaid Innovation (CMMI) for proposing the IOTA model, and particularly appreciate the clear, comprehensive and sobering analysis of the crisis in End Stage Renal Disease (ESRD) care and the lack of access to kidney transplant for those in need. We also appreciate the Proposal's comments about living kidney donation, which KTC believes is a critical part of the solution to eliminating the transplant shortage in our country. That said, while the proposal acknowledges that the data "underscores the need for initiatives and processes among transplant hospitals to encourage living donations," 89 Fed. Reg. at 43534, the actual proposed Model does not address the tools needed to create those incentives. As a result, **we are concerned that the Model is not sufficient to drive the needed systemic change that will allow transplant hospitals participating in the Model to increase living kidney donor transplantation.** We address the issue below, and propose several ways in which the Model could be modified to increase living donation.

About KTC: The Kidney Transplant Collaborative (KTC) is a national non-profit advocacy organization based in Washington, DC that is dedicated to identifying forward-thinking policy solutions to increase kidney transplants and decreasing many of the obstacles and financial barriers to kidney transplantation for potential kidney transplant recipients and donors. Through its advocacy and grant funding efforts, KTC works to improve the quality of life and survival rates for the tens of thousands of individuals with End Stage Renal Disease (ESRD) who could benefit from kidney transplantation as well as donors, potential donors, and the families of all involved.



KTC has engaged experts with technical, clinical, and quality expertise from the renal and transplant community, as well as those with lived experience as kidney donors and recipients, to serve on the Board of Directors and Expert Advisory Panel (EAP). The members of KTC’s Board and EAP play an important role in assessing the organization’s grant and policy priorities, as well as monitoring and closely tracking the outcomes of the grants selected for funding. Chaired by Dr. Louis Diamond, a leader in the transplant field and a transplant nephrologist for over 40 years, KTC is particularly focused in two areas: facilitating grants to advance kidney transplantation, as detailed on our website,¹ and advancing legislation, known as the LOVE Act,² to increase living donation in the United States. Given our focus on living donation, we address that issue below.

Living Donation in the United States Has Not Materially Increased in Over 20 Years: CMMI correctly notes that the core of the transplant problem in the United States is due to: “low rates of ESRD patients placed on kidney transplant hospitals’ waitlists, **a decline in living donors over the past 20 years** [bold added], and underutilization of available donor kidneys, coupled with increasing rates of donor kidney discards, and wide variation in kidney offer acceptance rates and donor kidney discards by region and across kidney transplant hospitals....[along with] substantial disparities in both deceased and living donor transplantation rates among structurally disadvantaged populations.” 89 Fed. Reg. at 43519.

CMMI accurately notes the profound significance of the decline in living donation. OPTN data document that over the past twenty years deceased donation has increased approximately 250%, while living donation has stagnated, if not declined. The statistics, year by year, are stark:



Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>

¹ <https://kidneytransplantcollaborative.com/grants/>
² <https://kidneytransplantcollaborative.com/love-act/>



In our view, there are two causes for this stagnation. First, by diffracting responsibility for living donation across two different agencies (CMS and HRSA) and dozens of individual transplant programs, CMS has created a system in which no single regulatory center is responsible for advancing living donation. Second, and as a result of the diffusion of responsibility across numerous actors Medicare regulations work against advancing living donation, rather than aiding those with ESRD in identifying living donors, and then assisting those potential living donors in navigating the complex and costly process of actually donating.

The IOTA Model Must Be Modified: Although the Medicare program has multiple regulations instructing transplant hospitals about maintaining systems to work with living donors, several key elements are missing, and should be addressed in the Proposed IOTA Model. The Proposal preamble also correctly notes that: “The evaluation or preparation of a living donor, the living donor’s donation of the kidney, and postoperative recovery services directly related to the living donor’s kidney donation are covered under Medicare. In addition, deductible and coinsurance requirements do not apply to living donors for services furnished to an individual in connection with the donation of a kidney for transplant surgery. Medicare Part B coverage includes the surgeon’s fees for performing the kidney transplant procedure and perioperative care. Medicare Part B also covers physician services for the living kidney donor without regard to whether the service would otherwise be covered by Medicare.” 89 Fed. Reg. at 43527. Despite this coverage, critical elements of a living donation program are *not* covered by Medicare today and impede living donors from participation in the program. Specifically, we wish to highlight two features of the living donor process that should be, but are not, included in the IOTA model: (1) living donation navigators, for both the potential recipient and for the potential donor; and (2) full cost reimbursement for living donors. Both are addressed below.

A. The Key to Eliminating the Transplant Waitlist is to Increase Living Donation.

The proposed model repeats in multiple sections that one of its goals is to increase living kidney donation. For example, at page 43525 the model states: “The goal of the proposed performance-based payments is: to increase the number of kidney transplants furnished to ESRD patients placed on a kidney transplant hospital’s waitlist; encourage investments in value-based care and quality improvement activities, particularly those that promote an equitable kidney transplant process prior to, during, and post transplantation for all patients; encourage better use of the current supply of deceased donor organs and greater provider and community collaborations to address medical and non-medical needs of patients; and increased awareness, education, and support for living donations.”³ Unfortunately, the Model’s proposed incentive (and disincentive) payments to transplant hospitals to increase deceased and living donation fail to provide any tools to help those centers increase living donation. At best, the proposal vaguely asserts that “IOTA participants could also invest in a living donation program,” 89 Fed. Reg. at 43551, to increase living donations and earn the incentive payments. But the specifics and tools, and

³ See also 89 Fed. Reg. at 43549 (“We believe IOTA participants may also increase the number of kidney transplants furnished to patients by improving or implementing greater education and support for living donors”).



authority to waive current Medicare regulatory restrictions that inhibit living donation, are missing.⁴

The need for living donation has been well documented. Just last year Dr. Arthur Matas (transplant surgeon, University of Minnesota) commented: “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.”⁵ Thus, while we applaud the IOTA Model’s focus on reducing kidney discards and increasing deceased donation, which we believe will materially increase the use of deceased donor organs, the real focus on the model should be on increasing living donation. And unfortunately, the model lacks any real tools for transplant programs *and others* to actually do so.

B. The Medicare Program Does Not Cover Navigators, and the Model Should Explicitly Do So – both for Transplant Centers and for Providers Touching ESRD Patients Before They Even Get to Transplant Centers.

For the past several decades, federal law and regulation has required transplant programs to have adequate support for living donors. *See* 42 C.F.R. § 482.94. Programs also need to have on staff an “independent living donor advocate team.” 42 C.F.R. § 482.98(d). Unfortunately, however, there is no federal program or Medicare regulation addressing living donation *before* a living donor arrives at a transplant hospital. While transplant programs appropriately help living donors through the surgical donation process, there remains a fundamental gap in both assisting potential recipients in identifying living donors or in helping potential living donors through the program so that they can actually show up and engage with the transplant program. And because recipients have difficulty identify living donors, and those potential donors have difficulty navigating the complex, multi-stage donation process, living donor rates have over the past twenty years.

Numerous studies have documented the need to assist ESRD patients in identifying and recruiting potential living donors – and has explained how giving ESRD patients a living donor navigator to assist in identifying potential donors directly translates into living donation rate increases at that center. Johns Hopkins University, for example, has used its CHAMPIONS program to great success. In a study of the program, they note:

approaching and recruiting live donors is a daunting and overwhelming experience for kidney transplant candidates. Current educational modalities or

⁴ *See* 59 Fed. Reg. at 43586 (requiring model participants to adhere to programs allowed only “under existing law and regulation”).

⁵ 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.



interventions do not adequately meet the needs of patients who would like to pursue and identify live donors. Education alone is not sufficient to decrease the anxiety and fear associated with approaching potential donors. In this trial, LDCs successfully helped increase comfort and decrease concerns associated with approaching a live donor. A dramatic proportion of participants (almost 50%) identified live donors, compared with matched controls for whom no live donors were identified.⁶

By intervening with those needing a transplant at an early stage, these issues can be overcome inexpensively and efficiently.⁷ Moreover, although the Proposed Model suggests that transplant programs adopt “educational programs” to attract more living donors, 89 Fed. Reg. at 43549, the literature quoted above makes clear that more education is not the answer. Those with ESRD need navigators to help identify and recruit potential living donors.

Even when potential living donors are identified, the drop off rate is astounding, and less than 10% of potential living donors who indicate they are willing to donate actually become living donors. A recent single center study at the Cleveland Clinic of thousands of potential living donors who completed a living donor application form showed remarkably high drop-off rates and an inability of one of the leading transplant programs to convert these interested individuals into living donors.⁸ The report indicates a massive drop-off rate in potential living donors from among 2501 individuals who completed the application form, with only 7.5% of individuals completing the intake form actually becoming living donors and 67% dropping off after completing the form before starting testing for compatibility.. Among other findings, the study noted:

⁶ 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.

⁷ See also Killian AC, Carter AJ, Reed RD, Shelton BA, Qu H, McLeod MC, Orandi BJ, Cannon RM, Anderson D, MacLennan PA, Kumar V, Hanaway M, Locke JE. Greater community vulnerability is associated with poor living donor navigator program fidelity. *Surgery*. 2022 Sep;172(3):997-1004. doi: 10.1016/j.surg.2022.04.033. Epub 2022 Jul 10. PMID: 35831221; PMCID: PMC9633042 (“The Living Donor Navigator (LDN) Program helps patients with end stage kidney disease identify living kidney donors and helps living donors navigate the complex evaluation process. LDN participants have demonstrated a 9-fold increased likelihood of donor screening and 7-fold increased likelihood of donor approval compared to nonparticipants”).

⁸ Cholin LK, Schold JD, Arrigain S, Poggio ED, Sedor JR, O’Toole JF, Augustine JJ, Wee AC, Huml AM. Characteristics of Potential and Actual Living Kidney Donors: A Single-center Experience. *Transplantation*. 2023 Apr 1;107(4):941-951. doi: 10.1097/TP.0000000000004357. Epub 2022 Nov 21. PMID: 36476994. See also Verbesey J, Bacigalupo A, Gilbert A, Li A, Zuttermeister C, Grafals M, Moore J, Javaid B, Abrams P, Ghasemian S, Cooper M. Living Kidney Donors: Battling High Attrition Rates During Evaluation Process. *Am J Transplant*. 2017; 17 (suppl 3). <https://atmeetingabstracts.com/abstract/living-kidney-donors-battling-high-attrition-rates-during-evaluation-process/>; Marlow NM, Kazley AS, Chavin KD, Simpson KN, Balliet W, Baliga PK. A patient navigator and education program for increasing potential living donors: a comparative observational study. *Clin Transplant*. 2016 May;30(5):619-27. doi: 10.1111/ctr.12728. Epub 2016 Mar 27. PMID: 26928471 (documenting a culturally sensitive methodology to attract minority living donor candidates).



- “Overall, 6 Living Kidney Donor applications were required for 1 successful donation;”
- None of the 8.4% of potential donors who met their recipients through social media made it to donation; and
- “Potential donors who were Black were much less likely to become actual donors. In addition, when looking at the donor to recipient relationship, first-degree relatives were much more likely to complete donation.” Yet, “in recent years...rates of related donors are declining, whereas the percentage of unrelated donors has been steadily increasing”.

Countering this real-world data, excellent national models exist to solve this program. For example, one of the nation’s leading transplant programs at the University of Alabama Birmingham (UAB) has been running a small donor navigator program and has reported outstanding results in translating willing individuals into actual living donors. One of several published studies on UAB’s success with what it refers to as the LDN program, reports as follows:

Implementation 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, suggesting that both advocacy and systems training are needed to increase actual LDKT rates. Importantly, the LDN Program was also demonstrated to have exceptional reach and effectiveness among African Americans, a population that historically has faced disparities in access to LDKT. In fact, African Americans represented 80.4% of program participants. Furthermore, compared to African American non-participants (standard of care patients), African American LDN Program participants were 8-fold more likely to have a donor screened and 7-fold more likely to have a donor approved. Moreover, these analyses by participant race demonstrated higher likelihood of screened donors and a similar likelihood of having an approved donor among African Americans compared to Caucasians.⁹

Unfortunately, the IOTA model does not adopt any of the elements of the LDN program or provide incentives for transplant programs to build on these ideas. Navigators are simply missing in the Model itself.

The notion of navigators is not new to CMS. Just this year CMS has created a direct payment program for “Principal Illness Navigators,” principally in the oncology and respiratory arenas. 88 Fed. Reg. at 78937 (Nov. 16, 2023). Unfortunately, the payment rate (1 RVU per hour of navigator services) is inadequate to support the specialized services needed for living donation navigation, and the requirement that recipients of navigator services pay a “co-pay,” 88 Fed.

⁹ 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.



Reg. at 78946 (“we do not have statutory authority to waive cost sharing for care management or other services”) makes the existing program a non-starter for living donors, who should not be asked for a co-payment. CMMI has the opportunity to resolve these issues through its waiver authority, and we urge the Agency to revise the IOTA model to do so.

For these reasons, we urge CMMI to revise the IOTA model, and to create specific program elements for both transplant hospitals *and nephrologists and primary care physicians working with ESRD patients upstream from transplantation* to engage navigators to assist potential recipients in identifying and recruiting potential donors, and then engaging with those individuals to help them navigate the entire donation process. While the proposed Model does urge transplant programs to coordinate with nephrologists and others, it is so unspecific, and provides no tools or other recommendations to do so, as to render the proposal unworkable. **The Model should propose specific direct reimbursement to all providers for facilitating specific recipient and potential donor navigator services to allow the program to succeed**, and living donors to increase their numbers in the transplant program.

If even half of the candidates who dropped out in the Cleveland Clinic study could be converted into living donors the IOTA model could radically increase living donation and reduce the wait list. Yet, the current Model does not address the problem where it is – *before* recipients and potential living donors ever get to a transplant program – and therefore in our view misses the mark on increasing living donation. The Model itself only projects an estimated increase of 2,625 transplants, both deceased and living, over the six-year period. Model, Table III, 89 Fed. Reg. at 43610. We urge CMMI to revise the Model to include specific incentive payments to all providers who provide these services and not just transplant hospitals, which will believe holds the promise of significantly increasing living donation rates.

C. The Medicare Program Does Not Provide Full Cost Reimbursement for Living Donors, and the Model Should Do So.

It is deeply unfortunate, and a significant policy failure, that the Medicare program has opted to explicitly prohibit the payment of living donor cost reimbursement. 42 C.F.R. § 413.402(d)(2)(iii) prohibits Medicare payment for donor expenses. Ironically, this prohibition even extends to transportation costs.¹⁰ The IOTA Model should include full cost reimbursement.

In the preamble to the Final Rule creating this regulation, CMS explained that the reason Medicare prohibits payment expenses is because the Health Resources and Services Administration (HRSA) may do so. 86 Fed. Reg. 73416, 73498 (Dec. 27, 2021) (“transportation and travel expenses of the living donor are not allowable Medicare costs. Programs outside of Medicare, such as that of the National Living Donor Assistance Center, may pay for transportation costs for living donors”). Further, the Proposal also states: “In the final rule, dated September 22, 2020, titled “Removing Financial Disincentives to Living Organ Donation” (85

¹⁰ We note that the policy is ironic given that transportation costs are paid in full if the donor is deceased. But if the donor is living, the donor is on his or her own and not even transportation costs will be reimbursed.



FR 59438), HRSA expanded the scope of qualified reimbursable expenses incurred by living donors under the Living Organ Donation Reimbursement Program to include lost wages and dependent care (childcare and elder care) expenses to further the goal of reducing financial barriers to living organ donation. The program previously only allowed for reimbursement of travel, lodging, meals, and incidental expenses. In the final notice, dated September 22, 2020, titled “Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Program Eligibility Guidelines,” HRSA increased the income eligibility threshold under the Living Organ Donation Reimbursement Program from 300 percent to 350 percent of the Federal Poverty Guidelines (85 FR 59531).” 89 Fed. Reg. at 43530; *see also* 42 C.F.R. § 121.14.

The reality is, however, that HRSA is *not* paying the transplant expenses of the overwhelming majority of potential living donors, and as a result thousands of potential living donors are not participating in the program. This is for two reasons – first HRSA means-tests both donor *and* recipient and will exclude any reimbursement if either does not meet the 350% test. (As an aside, HRSA’s own Advisory Committee recommended the threshold be set at 500% of the HHS poverty level, but HRSA ignored that recommendation.) Second, HRSA artificially limits the amount of payment to any living donor to no more than an estimated \$6,000 irrespective of actual expenses incurred (which are typically greater than that amount) due to concerns about the availability of funds. Although HRSA data about the National Living Donor Assistance Center (NLDAC) program which manages the living donor cost reimbursement program is not published, the available data (from 2017) indicates that less than 10% of living donors receive *any* cost reimbursement. As a result, living donors who cannot afford the out-of-pocket costs and lost wages incurred by living donation drop out of the system, even if they are medically qualified and physically prepared to donate.

There is ample literature demonstrating that the average living donor incurs approximately \$17,000 in expense to participate in the process.¹¹ This amount consists of \$6,650 (2023 dollars) of lost wages, \$4,000 of travel and lodging, \$6,000 in dependent and childcare costs, and other related costs.¹² It is evident that the HRSA reimbursement, if it occurs at all, is woefully inadequate to cover donor costs. The proposed model recognizes that transportation costs should be reimbursed, but only proposes to do so for *the recipient*. 89 Fed. Reg. at 43631, proposed section 512.458(a)(2) (allowing transportation costs for the “attributed patient” who is the recipient). All living donor costs (not just transportation) need to be accounted for and reimbursed as well. For that reason, **we call on CMMI to explicitly include full living donor cost reimbursement in the IOTA model, and explicitly waive the limitations of the regulation prohibiting Medicare cost reimbursement for any amounts not actually paid by HRSA or any other private insurer or other funding source.**

¹¹ *See* Brannon, Saving Lives While Saving Money, Regulation Summer 2023, available at <https://www.cato.org/regulation/summer-2023/saving-lives-while-saving-money>

¹² *Id.* citing numerous governmental and peer reviewed sources. *See also* McCormick F, Held PJ, Chertow GM, Peters TG, Roberts JP. Removing Disincentives to Kidney Donation: A Quantitative Analysis. *J Am Soc Nephrol.* 2019 Aug;30(8):1349-1357. doi: 10.1681/ASN.2019030242. Epub 2019 Jul 25. PMID: 31345987; PMCID: PMC6683718.



As noted above (note 4), the Proposed Model prohibits transplant programs from using Medicare funds to reimburse living donors for their out-of-pocket costs. 59 Fed. Reg. at 43586 (requiring model participants to adhere to programs allowed only “under existing law and regulation”). Although clearly permissible under NOTA, so long as the Medicare program prohibits cost reimbursement, many potential living donors will not participate in the program. To address this conflict, CMMI should explicitly waive the CMS regulation as part of the IOTA Model.

Conclusion: We appreciate the significant work CMMI has devoted to developing the IOTA Model, and we are optimistic that it will succeed in adding additional deceased donor organs to the transplant system. Unfortunately, however, there are not, and will not be, enough deceased donor kidneys to reduce, much less eliminate, the current transplant waitlist or meet the needs of those not yet on the waitlist. The answer to that issue lies in increasing living donation rates.

As noted above, there are several tangible ways in which living donation can be improved. The Proposed Model, however, does not provide any of these tools to transplant programs or others to create the landscape for living donation to succeed. We urge CMMI to modify the Model to allow for recipient and prospective donor navigators, and for full cost reimbursement to donors, to give transplant programs and upstream entities such as nephrology practices the opportunity to test how to increase living donation rates.

We welcome your questions and comments, and urge you to follow up with our counsel, David Farber, at dfarber@kslaw.com or (240)401.4800 with any further questions you may have. Thank you again for considering our comments, and we look forward to your implementation of an updated IOTA Model.

Sincerely,

Louis H. Diamond

Dr. Louis H. Diamond
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Kidney Transplant Collaborative (KTC)