NATIONAL KIDNEY FOUNDATION®

National Kidney Foundation

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Cc:
Abe Sutton, Director, Center for Medicare and Medicaid Innovation (CMMI)
Tom Duvall, Director, Division of Special Populations and Projects (DPSS), CMMI

February 9th, 2026

Re: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5544-P)

Dear Dr. Oz,

The National Kidney Foundation (NKF) is writing to share our feedback on the proposed regulation, CMS-5544-P, Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model.

As a threshold matter, we are grateful for the work the Innovation Center does to catalyze system change in kidney care. Innovating in government is no small matter; but rather is the function of the dedication and passion of countless public servants. On behalf of the patients we serve, we thank the Agency for its tireless efforts.

CMS cannot and should not stand alone in the implementation of its vision. The National Kidney Foundation aims to support the success of the IOTA Model through the channels at our disposal, including communication with patients, transplant centers, physicians, and clinicians, workshops, programs, and other convenings, and through other means that the Agency may find useful. We look forward to working with CMS to drive systems change at the intersection of aligned incentives, process improvement, education, new tools and technology, and, most importantly, the patient voice.

Thank you, and we look towards the future with you.

Summary Comments

- The National Kidney Foundation supports the IOTA Model and ongoing policy implementation to improve it consistent with our longstanding priority to reduce kidney discards/kidney non-use and improve transparency, shared decision-making, and patient activation in the transplant process.

- <u>IOTA Participants</u>: The National Kidney Foundation supports the proposed change to the low-volume threshold from 11 to 15 kidney transplants and the proposed change to exclude Veterans Health Administration (VHA) and Military Medical Treatment Facilities from the IOTA Model.
- <u>Performance Assessment</u>**:** The National Kidney Foundation supports the proposed update to the composite graft survival rate metric, the proposal to modify the composite graft survival rate scoring methodology to create a more even distribution of scoring for IOTA participants, and the proposed exclusion of multi-organ transplants from the composite graft survival rate exclusion and inclusion criteria.
- <u>Payment</u>: NKF supports the proposal to update the definition of Medicare kidney transplant to include transplants performed for MA patients while decreasing the maximum upside risk payment to $10,000 and the proposal to give CMS broader latitude to exercise flexibilities under Extreme and Uncontrollable Circumstances.
- <u>Other Requirements</u>:
    - The National Kidney Foundation supports the requirement that IOTA participants publicly post their patient selection criteria and the further requirement that adds audit of the public posting of those criteria.
    - NKF supports the proposed policy that IOTA participants post “written donor selection criteria in determining the suitability of candidates for donation.”
    - The National Kidney Foundation supports the Innovation Center’s proposal to disseminate quantitative and qualitative results of the model.
    - The National Kidney Foundation strongly supports the proposal to consolidate IOTA Participant patient selection criteria on the IOTA Model website.
    - The National Kidney Foundation supports the IOTA Model proposed policy to institute organ offer decline notifications for a subset of attributed patients in the model; however, we ask that the Innovation Center consider excluding organs that are ultimately discarded.
    - The National Kidney Foundation strongly supports both the requirement that IOTA participants review organ offer acceptance criteria with IOTA waitlist patients at least once every 6 months and the proposed clarifications in this rule.
    - The National Kidney Foundation strongly supports the proposed IOTA Model policy to notify patients when their status changes from active to inactive.
- <u>Beneficiary Protections</u>: The National Kidney Foundation generally supports the use of any levers available to the Innovation Center to ensure patients understand and are engaged in Innovation Center demonstrations.

Value-Based Care in Transplantation

Kidney care has long been a testing ground for the United States’ transition to value-based care. Kidney patients represent the existential challenge facing healthcare financing, namely the small proportion of seriously ill beneficiaries that account for a disproportionate amount of health spending. Kidney disease has been an ongoing focus of the CMS Innovation Center since the launch of the Comprehensive ESRD Care (CEC) Model in 2015. Since then, value-based approaches have proliferated across payers, healthcare settings, and healthcare products. The CMS Innovation Center continues to set the gold standard for these payment and quality value-based reforms, even as other payers institute their own incentive structures to control costs and improve quality of care.

NKF broadly supports the transition to value-based approaches in kidney transplantation. The journey to kidney transplant is marked by the types of challenges value-based care is well suited to solving:

- Absence of care navigation and care coordination leading to unnecessary attrition from the processes of being listed for a kidney transplant, living successfully with a kidney transplant, and becoming a living kidney donor.
- Lack of data-driven decision making contributing to organ wastage and other inefficiencies that impact the patient journey.
- Little accountability for process gaps that inform patient experience and outcomes.

Transitioning kidney transplant to value-based care will also bring new dynamics to be mindful of before they happen. As we see from the Kidney Care Choices (KCC) example, fee-for-service demonstrations inform commercial payer contracts with care coordination entities. However, while CMMI acts on its obligation to public transparency by aggregating and publishing performance results, commercial payers do not. Currently the commercial insurance market has no incentive to shift risk to care coordination entities, nor to consider reimbursement structures more progressive than the standard Center of Excellence contracts based on the quality outcome of one-year post-transplant survival of patient and graft and global case rate, i.e., the “best” outcomes for the lowest cost. However, if the IOTA Model is successful at increasing transplant rates while generating savings relative to dialysis, that dynamic may change. Alignment among payer incentives is essential. In fact, the greatest gap in the transition to value-based care are the appropriate authorities and policies to ensure multipayer alignment.

CVS Health (Aetna), Elevance (Anthem), Blue Cross/Blue Shield, and Cigna have the largest transplant specialty networks among payers. These are also in the top five largest health insurance companies in the country with contracts that span Medicare Advantage, the employer market, managed Medicaid, and the Affordable Care Act (ACA). Though the burden of dialysis on any single business line may be low, the burden of undiagnosed, unmanaged kidney disease and kidney failure on any single company is enormous. Yet, competing business lines in the same companies lack the full picture of the burden of kidney disease, limiting their willingness to invest in approaches that could improve access to kidney transplants. It is not incumbent upon the Innovation Center alone to raise the specter of this issue; however, we note it here for context. NKF continues to advance data and care transformation strategies through our flagship CKDintercept and Transplants4All initiatives to support identification of kidney patients in data sets held by healthcare organizations, integrated healthcare systems, and insurance companies and to demonstrate the return on investment for upstream and downstream care delivery transformations.

The IOTA Model, in conjunction with the ACCESS Model, the Ambulatory Specialty Care (ASC) Model, and other models that emphasize the early detection and management of chronic diseases, puts the entire trajectory of kidney care in the value-based context. As we bring kidney transplantation into that frame, NKF emphasizes the importance of transparency and alignment in best practice across all contracts. We will elevate this point with our colleagues in the Center for Medicare (CM) who may have a more appropriate set of regulatory tools to ensure beneficiaries are able to preserve their choice of the plan that best meets their needs and that risk sharing entities contracted with MA plans are, at minimum, held to a quality and transparency standard that meets the needs of the patients they serve.

For the time being, the Innovation Center continues to set the standard for these entities as they seek contracts outside the traditional fee-for-service value-based care environment. The Innovation Center may have a special role to play in shaping these frameworks as transformative technologies like xenotransplant advance towards the market. We know from our work with patients and the U.S. Food and Drug Administration (FDA), that patients are interested the option of a xenotransplanted kidney.[1] As the clinical trials proceed, it will be of the utmost importance to align regulatory, quality, and payment frameworks to the extent practicable to facilitate patient access.

In summary, we are grateful for the opportunity to work with the Innovation Center to set that standard on behalf of the current and future kidney patients who will experience the transplant journey shaped by value-based care.

Overview

The National Kidney Foundation's policy agenda in transplantation stems from a simple statistic: 14 people die each day on the kidney transplant waitlist while nearly 30 percent of kidneys procured for transplantation are thrown away. Research shows that patients who die on the list receive a median of 25 offers before death.[2] ***At the National Kidney Foundation, we wonder if the patients who died waiting for a transplant would agree that each one of those kidneys was bad?*** Broadly, we support the ongoing implementation of the IOTA Model and policy changes to improve it. Our support is rooted in support for system-wide changes to the set of incentives that preserve the status quo in which a small subset of individuals with kidney failure benefit from a kidney transplant, while others are denied more time and better health because of practices misaligned with patient needs, particularly the systemic decline of transplantable kidneys.

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[1] https://www.kidney.org/sites/default/files/2024-11/NKF_Xeno%20VoP_Final.pdf

[2] Mohan S, Yu M, Maclay LM, et al. Outcomes for Patients With a Deceased Donor Kidney Offer in the New Allocation System. Kidney Int Rep. 2025;10(4):1111-1121. Published 2025 Jan 20. doi:10.1016/j.ekir.2025.01.021

Improving the use of kidneys at risk of discard has been confounded by unregulated implementation of the distance-based kidney allocation system ("KAS 250"). KAS250 drastically increased the number of organ offers made to transplant centers at the same time that Organ Procurement Organizations (OPOs) began to improve organ donation rates and achieve organ transplantation rates (i.e., the placement of kidneys with transplant centers) in response to the implementation of the tiered accountability structure for OPOs.[3] [4] [5] The result was a system struggling under the weight of a changing, though improved, organ supply and a number of offers transplant centers could not meaningfully parse nor broadly had the capabilities or willingness to use. In the absence of meaningful oversight, allocation out of sequence (AOOS) grew to its highest levels ever, providing an advantage to a few centers that grew rapidly as a result while eroding overall fairness in allocation.[6] [7]

From NKF's perspective, growth in transplant volumes should not and need not come at the expense of fairness in allocation. Transplant volumes can grow as a result of a shared decision-making model between patients and transplant centers that puts education, transparency, and collaboration between the patient and the care team at the center of the process. This shared decision-making model has the patient's experience with kidney failure, dialysis, and the waitlist at the center. End-stage organ failure is one of the most difficult diagnoses to bear in modern medicine. Not every patient needs the so-called "perfect" kidney. Patient risk tolerance changes as patients spend more time on the list and more time on dialysis. The patient experience is not static, and neither is her calculus of risk-benefits. A system that honors the patient's voice begins with the effort to continually understand her experiences, her preferences, her values, and her needs.

Patient Story: *As someone who waited eight years on the kidney transplant waitlist, I experienced firsthand how exhausting and dangerous dialysis can be. Each treatment increases my risk of complications and mortality, with studies showing that long-term dialysis is associated with higher cardiovascular events, infections, and hospitalizations. Every session reminded me that my life was on hold, and the longer I waited, the more fragile my health became. When a kidney finally became available, it was not about it being "perfect"; it was about reclaiming my life, reducing the constant risks of dialysis, being able to contribute to the workforce again, care for my loved ones, and*

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[3] Mohan S, Yu M, Maclay LM, Adler JT, Huml AM, Schold JD, Husain SA. Outcomes for Patients With a Deceased Donor Kidney Offer in the New Allocation System. Kidney Int Rep. 2025 Jan 20;10(4):1111-1121. doi: 10.1016/j.ekir.2025.01.021. PMID: 40303214; PMCID: PMC12034855.

[4] Bae H, Sweat KR, Melcher ML, Ashlagi I. Organ Procurement Following the Centers for Medicare and Medicaid Services Performance Evaluations. JAMA Surg. 2026 Jan 1;161(1):97-100. doi: 10.1001/jamasurg.2025.5074. PMID: 41259060; PMCID: PMC12631566.

[5] Cron DC, Husain SA, King KL, Mohan S, Adler JT. Increased volume of organ offers and decreased efficiency of kidney placement under circle-based kidney allocation. Am J Transplant. 2023 Aug;23(8):1209-1220. doi: 10.1016/j.ajt.2023.05.005. Epub 2023 May 16. PMID: 37196709; PMCID: PMC10527286.

[6] Masotti M, Wood NL, Hart A, Schaffhausen CR. The impact of increasing out-of-sequence allocation on kidney transplant patient outcomes. Am J Transplant. 2025 Nov 21:S1600-6135(25)03120-X. doi: 10.1016/j.ajt.2025.11.014. Epub ahead of print. PMID: 41275919; PMCID: PMC12782076.

[7] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

participate fully in my community. Patients like me want to be included in these decisions because our voices, values, and tolerance for risk directly affect the outcomes that matter most to us. Every transplant offer is more than an organ; it is a chance to restore hope, dignity, and a life worth living.

B. Provisions of the Proposed Regulation

1. IOTA Participants

- **The National Kidney Foundation supports the proposed change to the low-volume threshold from 11 to 15 kidney transplants.** While only one additional center would be excluded from the IOTA Model, we appreciate the Innovation Center's sensitivity to the challenges small volume centers face in absorbing bad outcomes and the downstream impact this has on their ability to contract with commercial payors.
- **The National Kidney Foundation supports the proposed change to exclude Veterans Health Administration (VHA) and Military Medical Treatment Facilities from the IOTA Model with some regret.** We understand for practical purposes that the payment systems are different and complex for this group of transplant centers and that payment and quality incentives may have differential effects. We reaffirm the unique barriers faced by patients seeking transplants at VHA and Department of Defense (DoD) facilities and hope findings from the IOTA Model will galvanize the VA and DoD to consider how they can leverage their authorities to improve transplant access for veterans and military beneficiaries.

2. Performance Assessment

- **The National Kidney Foundation supports the proposed update to the composite graft survival rate metric to add a risk adjustment methodology that accounts for transplant recipient and donor patient characteristics**. The addition of a risk adjustment methodology is aligned with the overall goal of the model to encourage the transplantation of more clinically appropriate kidneys. We do not believe it is strictly necessary to align the risk adjustment methodology with that of the Scientific Registry of Transplant Recipients (SRTR). These risk adjustment methodologies serve different purposes for different measures. Innovation Center models are fundamentally behavior change projects and model policies should reflect that goal and therefore must be *simple, consistent over time, and not risk adjust away the precise variables contributing to heterogeneity in the non-use of clinically appropriate kidneys.* In addition, while we understand transplant centers' concerns, it is not worth the operational burden to the Center to align risk adjustment methodologies given the complexity of reproducing methodologies, as CMS will remember from the SRTR's difficulty reproducing the Organ Procurement Organization (OPO) metrics.
- **The National Kidney Foundation supports the proposal to modify the composite graft survival rate scoring methodology to create a more even distribution of scoring for IOTA participants.**
- **The National Kidney Foundation supports excluding multi-organ transplants from the composite graft survival rate exclusion and inclusion criteria.**

3. Payment

- **In general, NKF supports a variety of approaches to increase the dollars at risk in the IOTA Model.** We agree with the many other organizations engaged in the IOTA Model that finding mechanisms to engage Medicare Advantage (MA) patients in the model's incentive structure is important. While we understand that actuarially, the upside and downside risk in the model would be overall the same, we believe it is important to ensure there is an incentive structure that encourages transplant centers that do predominantly MA transplants to participate in the model. This is especially important because MA patients already face greater barriers to evaluation and listing because of prior authorization requirements and network restrictions. Over time, the Innovation Center could consider this lever, among others, to increase the incentives across IOTA Participants by increasing overall downside risk in the model, understanding the constraints posed by the non-interference clause. **Accordingly, we support the proposal to update the definition of Medicare kidney transplant to include transplants performed for MA patients while decreasing the maximum upside risk payment to $10,000.** We remain concerned by the attitude shared in public by some IOTA participants that they intend to take on the model's penalties as the price of not participating. In a vacuum, we acknowledge that a hospital is an independent organization free to make that choice. However, hospitals and transplant centers only exist as a function of patient needs. It is not acceptable that patients who are tied to a transplant center by circumstance are beholden to a center's choice not to participate in a mandatory Medicare demonstration.
- **The National Kidney Foundation supports giving CMS broader latitude to exercise flexibilities under Extreme and Uncontrollable Circumstances.**
- Acknowledging that this comment is out of scope, we still wish to highlight that transplant centers have largely ignored the encouragement and guidance provided by CMS to partner with outside organizations. We include this comment in the "Payment" section because these organizations cannot get approval from center administrators to spend funds on innovative partnerships prior to understanding their performance and determining whether the additional funds will cover the upfront partnership expenses. We would welcome the opportunity to discuss additional incentives or protections for IOTA participants that are willing to take a chance on partnerships to innovate.

4. Other Requirements

As we articulate elsewhere in this letter, NKF views transparency as central to improving patient-centricity and patient activation in kidney transplantation. ***Too often, the transplant patient journey does not belong to the patient.*** NKF supports the implementation of the transparency policies articulated in the proposed rule with the caveat that the implementation of these policies is of the utmost importance to ensure the information is activating and not overwhelming.

We understand that the Innovation Center's role is to adopt policy frameworks that allow for flexibility in implementation. Successful implementation of these policies will fall at the nexus of the learning and compliance activities by the Innovation Center, good faith efforts by model participants, and the support of organizations like NKF. For CMS' part, we encourage the Innovation Center to use all the tools at its disposal to ensure that transplant centers implement transparency requirements consistent with IOTA Model policies and with patient-centricity at the fore.

Change is a process. Even with the appropriate motivation in the form of aligned incentives, systems must be taught to change to achieve sustainable results for patients. Unintended consequences emerge when policies are promulgated that organizations are not prepared to operate. We hope our support for the transparency policies in the IOTA Model will be the start of a collaboration between CMS, the patient community, IOTA participants, and NKF to support patient-centered implementation of policy-driven changes to the transplant process. For example, NKF could consider a patient-led workshop to create patient-friendly notification templates that transplant centers could download and use to support the adoption of more transparent processes.

A. (1) Publication of Patient Selection Criteria for Kidney Transplant Evaluations

The National Kidney Foundation supports the requirement that IOTA participants publicly post their patient selection criteria and the further requirement that adds audit of the public posting of those criteria. Public posting of patient selection criteria is essential to patient choice, closing gaps in transplant referral, shared decision-making, and expectation setting for patients about the depth and breadth of the transplant process. Importantly, public posting of patient selection criteria gives nephrologists the opportunity to support the resolution of barriers to transplant *prior to* transplant referral. In our experience, beyond the most obvious medical exclusions, many patients are either declined to be evaluated or declined for listing due to modifiable barriers, many of which could be addressed ahead of their evaluation if they were known to the patient. A non-exhaustive list of these criteria are provided in Appendix I.

The term patient selection criteria is defined at 42 CFR 482.90 to mean the criteria used to determine a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. This regulatory definition is broad and may be interpreted to mean different things by different centers. Appendix X of the State Operational Manual (SOM) clarifies that written selection criteria must be followed for selection of transplant candidates to be placed on the *transplant waiting list.* Criteria writ large are used to make decisions about a patient's suitability for transplant at multiple points in the process including evaluation, listing, active listing, and transplantation. We believe the most meaningful set of criteria for a patient are those that inform the patient about the barriers she or he must overcome *to be evaluated*. **We recommend the Innovation Center promulgate a specific definition of patient selection criteria for the purposes of the IOTA Model.** The IOTA Model is an optimal testing ground for determining whether a larger change to the Conditions of Participant would be warranted. If the Innovation Center's intention is for patient selection criteria to mean the criteria used to make decisions about access to the list, the definition should clarify that patient selection criteria refer to the criteria used to make decisions about *active* waitlisting.

We further recommend that the Innovation Center provide a list of questions to generate criteria areas that IOTA participants are required to respond to. We acknowledge that this effort is complex because some criteria are concrete, but many are not. We would be pleased to support CMMI in the development of a set of questions that would elucidate a set of concrete threshold criteria to which IOTA participants would respond. Initially, this policy would result in a great deal of "maybes," but over time could encourage nephrologists and transplant centers to think critically about how to communicate with patients about true medical exclusions versus surmountable barriers with appropriate support. This requirement would leave transplant teams full discretion for who is evaluated, listed, and transplanted but gives patients the roadmap they need to understand their own barriers and things they may be able to do to make themselves better candidates. In general, for this information to be activating for patients, it must help the patient understand the barrier, whether being evaluated, listed, or kept active on the list. For example, the question "does this center have a BMI requirement" that generates an answer of "yes," "no," or "maybe" is not meaningful for a patient. The question "what is this center's BMI criteria" and answer of "BMI of 45 or less" gives the patient and her or his clinician a sense of the goal.

NKF supports the proposed policy that IOTA participants post "written donor selection criteria in determining the suitability of candidates for donation." Similarly to the other proposed requirements in this section, transparency about a center's concrete threshold requirements for donation would allow potential donors to be better prepared. We note similar issues as above: the Innovation Center may wish to be more specific about what stage of the living donor process the written donor selection criteria are intended to target, and we suggest a process to support implementation of this proposed policy that would identify concrete thresholds for evaluation and/or donation.

(2) Publication of IOTA Participant Selection Criteria

The National Kidney Foundation supports the Innovation Center's proposal to disseminate quantitative and qualitative results of the model. We are especially interested in the proposal to provide insights into patient experience of care and quality of life. We note that the transformation of CMS measures into legible ratings and rankings that can help patients parse the difference between centers in a meaningful way is a notoriously difficult task, for example the Quality of Patient Care Five-Star Rating system example. This is not to say that the Innovation Center should not pursue this laudable goal. We aim to be a meaningful partner in identifying solutions to advance this proposal.

The National Kidney Foundation strongly supports the proposal to consolidate IOTA Participant patient selection criteria on the IOTA Model website. As we have commented elsewhere in this letter, transparency for the sake of transparency is not necessarily meaningful for patients. We strongly agree with other comments on previous IOTA Model rules that centralization is important. CMS' requirement for the posting of patient selection criteria specifies the information be posted on the centers' website. A patient navigating transplant options in Texas, would need to look at 15 different websites to compare patient selection criteria. This proposed policy is also consistent with NKF's overall vision for a centralized OPTN-operated digital point of entry to the transplant system.

(3) Transparency Into Kidney Transplant Organ Offers

The National Kidney Foundation supports the IOTA Model proposed policy to institute organ offer decline notifications for a subset of attributed patients in the model; however, we ask that the Innovation Center consider excluding organs that are ultimately discarded. Our support for the proposed policy is rooted in the belief that patients deserve the option to know about the decisions that are being made on their behalf, both as a matter of transparency and as a means of ensuring decisions are aligned with their actual preferences. We believe that if the decision was the right decision for the patient, the center should be able to convey that decision to the patient, like any other kind of counseling. While we believe the 3-years of wait time threshold is arbitrary and would prefer decline notifications to begin immediately following waitlisting, we understand the need to balance the needs of different constituencies. We hope the Innovation Center will continue to refine the policy as we learn more about how it works for patients and the physicians, clinicians, and centers that serve them.

Consistent with comments made elsewhere in this letter, implementation is of the utmost importance. We do not want to pretend that many patients will not be shocked, dismayed, and perhaps angry when they learn even one offer was declined without their knowledge. While some would argue that this is a reason to maintain current practice, we would respond that the system should not have ever been allowed to become such a black box that trust between the patient and her or his care team cannot be maintained without withholding basic information relevant to the journey to transplant. We acknowledge that change is difficult. Change is also often necessary.

For the implementation of offer transparency to be activating and patient-centered, IOTA participants must educate patients as soon as the evaluation and listing process begins. That education must be provided on a continuous basis throughout the patient's transplant journey.

Patient Perspective: *"Patient trust in their transplant team is critical not only while waiting for a transplant, but after transplantation, when long-term graft survival depends on adherence to* *their teams' medical recommendations. Undermining trust by failing to educate patients up front may negatively impact outcomes if patients lose confidence in their center's guidance."*

Notably, we do not agree that any IOTA participant will need to notify patients of "hundreds" of offers, as other groups have stated. The enormous volume of offers seen at a national level is a function of many kidneys being offered many times. This dynamic is not observed at the individual level. Nevertheless, ongoing education and counseling are essential to ensure no patient is caught off guard by an unexpected notification. To further safeguard against patient anxiety, we strongly support linking the notification to real-time communication to support the patient's understanding of what the decline means.

We note that the transparency policies promulgated in the proposed rule need not be tied to transplant center-specific reporting systems. We support the Innovation Center's work with the Health Resources and Services Administration (HRSA) on "operational assistance to help make sure this information is easily accessible…and in a format that [can] be easily shared with eligible IOTA waitlist beneficiaries." We believe the modernization of the Organ Procurement and Transplant Network (OPTN) provides a new opportunity to centralize reporting to patients through a "front door" to the transplant system operated by the OPTN. In the 2025 manuscript, *Patient and Provider Attitudes Toward Patient-Facing Kidney Organ Offer Reporting*, the authors recommend that organ offer reports be provided to patients and their care teams directly through the OPTN, rather than by the transplant center, as the OPTN is the stakeholder with the best access to the data that would make these reports most meaningful, including the final organ disposition and offers that were bypassed because of expedited placement efforts. Husain et al. further suggest a "personal offer portal" where patients could manage their preferences and receive notifications with a cadence and level of detail that they are most comfortable with. This centralization would also allow the development and implementation of standardized report features designed with patient and provider input, rather than center-developed materials whose development may not account for patient preferences.

Finally, we read with interest the Innovation Center's thoughts about the provision of a standardized notification template. Should the Innovation Center be interested in the creation of this tool, NKF would be pleased to discuss partnering with CMS and the patient community to co-create it.

(4) Review of Acceptance Criteria

Consistent with our longstanding position that shared decision-making in transplant is a crucial driver of patient-centricity and improved utilization of organs, the National Kidney Foundation strongly supports both the requirement that IOTA participants review organ offer acceptance criteria with IOTA waitlist patients at least once every 6 months and the proposed clarifications in this rule. The proposed definition of "transplant organ offer acceptance criteria" as individualized patient acceptance parameters is aligned with the following idea shared by a patient: *"transplant centers should be required to make an individual organ offer plan for each patient."*

As regarding other comments we make herein, we recommend that discussions about acceptance criteria begin early, as soon as the time of evaluation, and again at the time of listing. The framework for this conversation already exists at many centers since policies and procedures, including the OPTN policy requirement at 5.3.C *Informed Consent for Kidneys Based on KDPI Greater than 85%,* require patients to specifically consent to receive high KDPI kidneys. Receiving Hep C positive offers also requires informed consent by the patient. These early discussions should be expanded to include:

- Reasons why organ offers are made and then declined,
- How aggressive the center is in taking marginal organs,
- The most common reasons an organ is declined, and that
- Changes to the system to increase geographic equity caused an increase in organ offers.

Considering the ongoing modernization of the transplant system and the opportunity to procure and deploy more sophisticated technology, we would be interested in discussing the concept of developing and implementing *individualized* organ offer filters with our federal partners working to improve transplantation across the Department of Health and Human Services. Individualized organ offer filters could decrease the number of inappropriate offers surgeons must sift through, improving both transparency and center burden. We do understand such a proposal is far outside the Innovation Center's authorities and mandate.

(5) Change in Waitlist Status

The National Kidney Foundation strongly supports the proposed IOTA Model policy to notify patients when their status changes from active to inactive. Though notifications to patients on their status do happen, this practice is highly variable across centers. NKF recently commented on a similar though narrower policy proposal through the OPTN comment process. Understanding her or his status on the waitlist is one of the most critical pieces of information that a patient needs to understand about potential for transplant. Relative to the proposed OPTN policy, the proposed IOTA Model policy has several additional components we believe to be exceptionally important, specifically the information provided with the notification about how the patient may become active again, and the concurrent notification to the dialysis facility and the patient's nephrologist. Without these additional requirements, the notification of this essential information risks becoming another notice sent to the patient through the patient portal that is never read.

For the purposes of compliance, we recommend the Innovation Center ensure that all notifications are tracked in the medical record. Notifications not recorded in the medical record technically did not occur. A record of the notification must be visible in the patient's chart to everyone, including and especially, the patient.

5. Beneficiary Protections

The National Kidney Foundation generally supports the use of any levers available to the Innovation Center to ensure patients understand and are engaged in Innovation Center demonstrations. We note the importance of monitoring, compliance, and learning activities to encourage IOTA participants to follow not just the letter of the law, but also its patient-centered intention. As part of the subregulatory process of approving beneficiary notification templates, we suggest that the Innovation Center add a requirement that the notification be made in plain language, including the areas of focus for the IOTA Model to provide context, and inviting comments to transplant center staff and CMS about their experience at an IOTA participant center.

An example of where the patient became an afterthought is offered below:

Patient Story*: A patient received an IOTA beneficiary notice this week, has no idea what it was and the impression was lots of changes within the transplant system and worry about how this might impact time to transplant. The letter included a list of organ offer acceptance criteria that was supposedly selected by the patient, most of which he'd never seen before or heard of. None of it was in patient friendly language and it created confusion, anxiety, and fear. The patient went to ChatGPT to try to understand the organ offer acceptance criteria page. These notices should be brief, 6th grade level and be very clear that the IOTA model includes metrics that are being collected and encouragement to increase the number of transplants and the availability of more organs, while carefully monitoring outcomes with transplant centers being rewarded for improvements. They should be reassured that this is not a change to their wait time or status. A hopeful statement would be helpful for patients to understand that the intent of the IOTA is to increase access to transplant. It is possible the model could improve the number of transplants their center is doing and positively impact their status, or make more organs available to them, but whatever is said should not make them feel anxious!*

C. Request for Information (RFIs) on Topics Relevant to the IOTA Model

1. Pre-Transplantation Access Process Measure

The National Kidney Foundation has sustained concerns about the lack of data about and accountability for the pre-transplant process. We are encouraged by the Request for Information (RFI) in the proposed rule, and believe it to be well timed with efforts by the Health Resources and Services Administration (HRSA) to collect information from transplant centers about when individuals are first referred to them for an organ transplant, as well as the results of their transplant evaluation and selection as a transplant candidate.

In July of 2025, NKF offered supportive comments on all three OPTN data collection instruments. In those comments, we noted the Pre-Waitlist Transplant Referral Form and the Pre-Waitlist Transplant Evaluation Forms would be essential components of improving accountability because they provide insight into gaps in care delivery across our nation's 257 transplant centers. We commented that these instruments would provide visibility into system-wide heterogeneity in pre-waitlist processes, thereby elucidating patterns in care delivery and giving policymakers and the public opportunity to understand where gaps are appropriate and where they are not. Where care gaps are not appropriate, we noted the need for further accountability to patients and the public to assure the fairness and effectiveness of the U.S. transplant system. We emphasize those comments here, as well, for context.

One of the strengths of the National Kidney Foundation is that we drive systems change in multiple domains. Policy and system-level incentives are one way to encourage change, though not the only way. Through our Transplants4All initiative, NKF is advancing work that may help inform the Innovation Center's thinking on pre-transplant access, both in terms of specific measurement targets and the processes needed for the system to act on those targets.

The NKF's Transplants4All Team is leading *Changing Lives Through Transplant*, a state-based, collective impact model bringing together key stakeholders with the goal of increasing kidney transplantation in Missouri. From CMS' perspective, collective impact projects may be perceived as quality improvement efforts, separate and distinct from the work of payment and regulatory policy. We see quality improvement and change management initiatives, payment policies, and regulatory policies as natural allies, serving as catalysts of systems change, and being most effective when applied in combination. The output of our Changing Lives Through Transplant stakeholder convening elevated several recommendations that we believe will serve as learning labs for what might scale at a national level, with support from CMS:

- Execute quality improvement projects from CKD diagnosis and management through evaluation, including embedded education and referral processes,
- Convene a workgroup to develop a pilot to identify CKD patients for transplant referral, in collaboration with health plans,
- Research perceived barriers among MO general nephrologists to referring CKD patients for preemptive transplants and build solutions to address key challenges,
- Pilot and evaluate the impact of a business case toolkit for transplant program growth to increase living donation,
- Convene a workgroup to define, design, and implement a shared transplant patient referral form, including basic critical information, and
- Launch a pilot using Community Health Workers to provide navigation services in a transplant setting, including addressing support needs.

We also expect these efforts will surface potential measure concepts. For example, in designing a quality improvement project for nephrology practices, the NKF team brainstormed a measure concept that identifies patients who are “eligible” for transplant care (Stages 3b and 4) that measures whether patients received care at a transplant center, i.e., started an evaluation. Another possible measure concept might be eGFR at the time of referral.

As CMS is aware, policies that incentivize transplantation have been challenging to develop and have not moved the needle on access to transplant, or even access to the waitlist, as intended. Despite the widespread understanding that preemptive transplant is the best treatment we have to offer, only 3 to 4% of people are transplanted before dialysis. It is clear more targeted policies are needed, and that those policies must be rooted in a comprehensive understanding of the system-level barriers that continue to create bottlenecks in preemptive transplant, referral, evaluation, and waitlisting. We are eager to share our insights from Transplants4All. In combination with new OPTN data, and opportunities like the evolution of the Kidney Care Choices (KCC) Model, we are entering an era of unprecedented opportunity to close gaps in pre-transplant access at the national level.

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In conclusion, the National Kidney Foundation (NKF) continues to support the IOTA Model, with a special emphasis on the goals of improving utilization through shared decision-making, and the patient journey through activating transparency policies that make transplant feel more accessible and patient centered. As CMS is aware, end-stage kidney failure is transformative diagnosis. Too many patients don’t survive it or are buried under the physical and physiological strain of managing the treatment and consequences of kidney failure. Each step forward, even when incremental, fulfils the promise to patients to seek better for them, and those who will be afflicted in the future. We thank CMS for its assiduous work on the IOTA Model and look forward to continued partnership.

Sincerely,

Dr. Jesse Roach
Senior Vice President, Government Relations
The National Kidney Foundation

Appendix I.

Category	**Items (Examples**
Medical	
	BMI Threshold
	Use of Oxygen
	History of Cancer
	Infection/Wounds
	Cardiac Status
Age	
Adherence	
	Frequency of Missed Dialysis Sessions
	Dialysis Labs
Financial and Insurance Stability	
	Fully Insured
Substance Use	
Psychosocial Support	
Social Issues	
	Access to Transportation
	Access to Food Security
Physical Strength/Endurance	
	6-minute Walk Test
	Strength Test
Cognitive Impairment	

Vaccine Screening	
Individual Comorbidities	
	History of Psychiatric Disease
Surgical History	
Medical Complications	