February 9, 2026

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services

Abe Sutton
Director
Centers for Medicare & Medicaid Innovation

Department of Health and Human Services
Attention: CMS-5544-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model CMS 5535-P [RIN 0938-AV65]

Dear Administrator Oz and Director Sutton:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for your leadership on, and commitment to, kidney health.

Dedicated to maximizing access to kidney transplantation for every American who could benefit, ASN has been a strong proponent for more than a decade of the principles now being tested in the Increasing Organ Transplant Access (IOTA) model. The society has appreciated the opportunity to provide input to CMMI regarding this important model numerous times and is gratified that many of the concepts ASN has recommended are included in the current model design.

ASN has closely monitored the kidney transplant community's experiences with the model since its July 1, 2025, start date and has provided education to stakeholders participating in the model to improve their likelihood of success in achieving its goals. Based on these interactions, informed by transplant nephrology experts in ASN's leadership, and reflecting the society's commitment to help CMMI strengthen the model to benefit kidney transplant recipients and candidates, ASN offers 10 key recommendations in response to the December 2025 proposed IOTA rule. More detailed explanations of the society's feedback follow.

ASN will organize its comments (both key recommendations and more detailed explanations) in the order in which CMMI addressed the issues in its proposed rule, starting with the low volume threshold, continuing on to Department of Veterans Affairs medical facilities and military medical hospitals, risk adjustment for composite graft survival measure, multi-organ transplant, quality domain scoring, Medicare Advantage beneficiaries and IOTA, transparency requirements, the RFI on pre-transplant access measure, and concluding by addressing allocation out-of-

sequence. While this response highlights many of ASN's recommendations for transforming the broader U.S. transplant system, the society welcomes an opportunity to meet with CMS and CMMI to discuss them further.

Key ASN Recommendations

1. Institute a risk adjustment model for the Quality Domain with a small number of components that have a well-demonstrated effect on patient outcomes and are clinically coherent.
2. Strengthen the financial relevance of IOTA for participating transplant centers to increase meaningful engagement to achieve the model goals, including:
    - Create greater consequences for poor performance on long-term patient outcome in the Quality Domain and assign points across deciles instead of quintiles.
    - Increase the magnitude of downside risk payments.
    - Identify a pathway to include people with Medicare Advantage (MA) plans, such as one of the approaches ASN recommends in more detail in this letter.
3. Establish transparency regarding MA plans and how people with kidney failure and kidney transplants fare in terms of access, outcomes, and quality of care to foster understanding of opportunities for improvement in payment, plan design, and patient-centeredness—including, but not limited to, in IOTA. More detailed feedback is included in this letter.
4. Share center-specific evaluation criteria for both prospective transplant recipients and living donors, providing publicly available information about which types of recipients or donors may or may not be a good fit for the expertise of a given transplant center so that people can make more informed choices about where to consider pursuing care or donation.
5. Provide waitlisted patients with retrospective, asynchronous information regarding organ offer declines made on their behalf every six months.
    - Begin sharing this information without delay, rejecting CMMI's proposal to wait until a patient's third year on the transplant waitlist.
    - Institute other ASN recommendations to minimize burden of sharing organ offer declines on participating transplant centers.
    - Consider whether retrospective conversations regarding organ offer declines warrant development of a new billing code.
6. Notify patients when their waitlist status changes from active to inactive—and create a mechanism allowing patients to view their status in close to real-time via an online platform.
7. Develop a platform that allows prospective patients and donors to view center-specific information about transplant centers (such as evaluation criteria), compare centers, and access information about their own care (such as organ offer declines or waitlist status).
    - Advance, through this approach, both the goal of patient-centered transparency to improve navigability and the goal of minimized administrative burden on transplant centers, which would otherwise have to dedicate resources to collating and sharing this information that could otherwise be dedicated to patient care.
8. Pursue development of a pre-transplant access measure(s) to inform benchmarking and performance improvement—not for payment purposes—and assess whether IOTA is the optimal venue to pilot or utilize these measure(s).
9. Consider approaches to ensure IOTA does not inadvertently incentivize or inappropriately reward use of kidneys allocated out of sequence (AOOS).
10. Work towards adoption of many of IOTA's hallmarks in the broader U.S. transplant system.

Low Volume Threshold

CMMI requests input on a new low volume threshold. ASN supports CMMI's proposal that a kidney transplant hospital must have performed a minimum of 15 kidney transplants to patients aged 18 years or older annually, regardless of payer, in each of the baseline years, rather than a minimum of 11 kidney transplants.

Department of Veterans Affairs Medical Facilities and Military Medical Hospitals

CMMI requests feedback on its proposal to exclude kidney transplant hospitals that are Department of Veterans Affairs (VA) medical facilities or military medical hospitals from the IOTA model. CMMI notes that the Medicare program does not provide coverage for services furnished by a federal provider, federal agency, or any other government entity, whether the services are paid for directly or indirectly by a government source, and that VA medical facilities and military transplant facilities operate under different payment structures, regulatory frameworks, and patient populations compared to Medicare-participating hospitals. ASN concurs with CMMI's rationale that, for these reasons, it is appropriate to exclude these facilities from IOTA.

Risk Adjustment for Composite Graft Survival Measure

ASN strongly supports CMMI's proposal to add risk adjustment to the composite graft survival score (the Quality Domain). The society appreciates CMMI's recognition that short-term outcomes have historically achieved the preponderance of focus at the expense of other outcomes that are also important to patients, such as access to kidney transplantation itself. ASN commends IOTA's appropriate focus on increasing kidney transplant rates. Some centers that successfully increase transplant rates (performing well in the Achievement Domain) will do so by accepting more complex patients and organs. Absent risk-adjustment, these centers are likely to face lower scores in the Quality Domain. ASN concurs that a risk-adjusted composite graft survival measure preserves the incentive to deliver high-quality outcomes while ensuring that centers are not penalized by increasing access to transplants. Adding risk adjustment will help minimize the sense among participants that they would be harmed by transplanting more complex patients who are nonetheless good candidates to benefit.

ASN appreciates that CMMI aims to propose a risk adjustment model that is clinically coherent, with components that have a well-demonstrated effect on patient outcomes. The society particularly supports the inclusion of the following components in a risk adjustment model (listed in alphabetical order). These components are easily verifiable, and ample evidence exists that they influence future transplant outcomes:

Recipient characteristics	**Donor characteristics**
• Age • Diabetes • Distance from transplant center • Hypertension • Insurance status • Pre-transplant dialysis time • Prior transplant history	• Age • CVA as cause of death • DCD • Diabetes • Sex

ASN recommends against including functional status, as it is difficult to measure uniformly and current data may not be readily available or reliable. The society also notes that while panel reactive antibody (PRA) status may not be an unreasonable component to consider including, it is misidentified in the proposed rule as “plasma renin activity” levels.

Multi-Organ Transplant

CMMI proposes to exclude multi-organ transplants, except for kidney/pancreas transplants, from the composite graft survival rate metric (Quality Domain). ASN supports CMMI’s proposal and agrees that multi-organ transplants should remain in the Achievement Domain. However, CMMI should clarify that, in the case of kidney/pancreas transplant, only the kidney outcome counts towards achievement and quality outcomes. While this point may seem intuitive, it is not clearly stated in the draft proposal (importantly, pancreas graft survival within the first few years post-transplant is lower than that of the kidney part of SPK or kidney alone). As CMMI notes, multi-organ transplants are highly complex procedures with increased complexity of clinical outcomes. Additionally, very few multi-organ transplants are performed. Recognizing this is a small population of patients with elevated risks of outlier outcomes, ASN does not believe it would be possible to adequately risk-adjust.

Quality Domain Scoring

CMMI proposes to reallocate the number of points across performance quintiles that IOTA participants falling into each quintile can earn. ASN generally supports this recommendation but suggests a key modification the society believes will strengthen CMMI’s intent with this proposed change. The new approach to the quintiles creates greater consequences for poor performers, which ASN believes is appropriate. The society has previously commented on its desire to see long-term post-transplant access receive greater weight in IOTA and commends CMMI for proposing this modification, which ASN believes will incentivize participants to focus on these outcomes more than in the current model design.

If the proposed risk adjustment is finalized, ASN is even more supportive of instituting more significant point penalties for poor performance in this domain.

However, ASN believes CMMI’s proposal could be strengthened by moving from quintiles to deciles while maintaining a proportional number of points earned, across deciles. This approach would create a smoother gradient across performance categories while keeping the steeper penalties CMMI proposed for poor performers. ASN notes that smaller IOTA participants would face greater risk with the larger “cliffs” across quintile points, which the society’s proposed alternative would help mitigate. The society acknowledges that there may be statistical issues by creating ten performance categories instead of five, as the number of IOTA participants in each decile will be relatively small, but urges CMMI to strongly consider its proposed alternative.

TABLE 2: PROPOSED COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile relative to target OR for comparison	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	5
20th Percentile	N/A	Less than 20th percentile	0

Table 1. ASN Alternative Proposed Composite Graft Survival Rate Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th percentile relative to target OR for comparison	Equals 80th percentile	Greater than 80th (should be N/A)	20
70th	Equals 70th	Less than 80th	17.5
60th	Equals 60th	Less than 70th	15
50th	Equals 50th	Less than 60th	12.5
40th	Equals 40th	Less than 50th	10
30th	Equals 30th	Less than 40th	7.5
20th	Equals 20th	Less than 30th	5
10th	Equals 10th	Less than 20th	2.5
10th	N/A	Less than 10th	0

Medicare Advantage Beneficiaries and IOTA

CMMI poses numerous questions about the legality, feasibility, and desirability of including MA beneficiaries in IOTA, building on considerations discussed in the first IOTA proposed and final rules. ASN previously supported the inclusion of MA beneficiaries in IOTA and continues to do so in principle, reflecting the society's belief that IOTA drives changes that are likely to be beneficial for all patients, regardless of primary payer (such as increased access to transplantation, improved long-term outcomes, and greater transparency). The society also understands there may be impediments to updating the definition of Medicare kidney transplant to include MA beneficiaries and, while ASN does not have legal expertise, offers several considerations that may help advance the objectives desired by their inclusion.

Increasing kidney transplantation volumes among MA enrollees may be challenging but is important. Evidence shows that compared to traditional Medicare enrollees with kidney failure, MA enrollees with kidney failure are more likely to be dually eligible for Medicaid and to be from lower socioeconomic status groups that have historically had lower access to transplantation.[i] Without adequate risk adjustment and policy guardrails, transplant centers may be disincentivized from listing or transplanting MA enrollees, even as evidence shows this population faces structural barriers to access. Absent appropriate risk adjustment and safeguards, accountability models may create incentives for transplant centers to preferentially serve lower-risk populations, thereby undermining efforts to expand equitable access for MA beneficiaries.

Consequently, it is reasonable to hypothesize that growing transplant volumes among MA enrollees should be more challenging for transplant centers than growing transplant volumes among traditional Medicare enrollees (though this challenge also constitutes an opportunity to increase access to transplantation for a population who are clinically good candidates but who receive kidney transplants less often than would be ideal at present). Recent research shows that relative to patients with traditional Medicare insurance, MA enrollees had an 18-24% lower likelihood of being waitlisted for transplant by one year following initiation of dialysis treatment.[ii] These results persisted after controlling for differences in the clinical, demographic, and socioeconomic characteristics of patients and their neighborhoods. Consequently, the authors concluded that it would be important to monitor transparently the quality of transplant-related care provided through MA plans and to verify that beneficiaries' transplant access was not detrimentally impeded by narrow networks of transplant hospitals or specialist physicians.[iii]

MA enrollees' transplants are already included in the Achievement metric. As shares of Medicare beneficiaries with kidney failure, MA enrollment is increasing while traditional Medicare fee-for-service (FFS) enrollment is decreasing. Thus, the goal of growing total kidney transplant volumes can be most efficiently achieved with a strategy of incentivizing MA transplants in the same way traditional Medicare transplants are incentivized in IOTA. Since both MA transplants and traditional Medicare transplants are counted in the IOTA model's Achievement metric, ASN believes the strategy is already implemented to a significant degree and commends CMMI on this achievement. However, inclusion in the Achievement metric alone may not fully overcome structural barriers unique to MA, such as network limitations and administrative requirements. This dynamic underscores the importance of ongoing monitoring and refinement to ensure incentives translate into real-world access, and that Medicare beneficiaries have similar access to optimal therapies whether covered by Medicare Advantage plans or fee-for-service mechanisms.

The overall incentive to grow transplant volumes is determined by the total upside / downside risk summed over the entire year, and not the distribution of that risk across the transplants performed during the year. ASN has previously suggested that CMMI could include the MA patient population in the model by applying incentives attached to Organ Acquisition Costs that Medicare covers for MA beneficiaries who receive a transplant. The society continues to believe that this approach warrants consideration. While ASN continues to support the inclusion of MA beneficiaries in IOTA, ultimately, the society believes that the magnitude of the financial incentive summed over the year is more important in driving behavior change than spreading the incentives around to more beneficiary types.

CMMI notes that if MA beneficiaries are included to a greater degree in IOTA, it would decrease the maximum upside payment from $15,000 to $10,000, substantially reducing it from ASN's original recommendation (finalized by CMMI at $15,000, a decision the society applauded and continues to support). ASN realizes that this potential reduction in maximum upside payments reflects CMMI's desire to keep the model's new savings projections consistent with the original projections. However, ASN recommends that if MA patients are to be included, it would be preferable to offset by increasing the magnitude of downside risk payments (e.g. greater than $2,000) rather than reducing the maximum upside payment.

Critically, reducing the upside incentive risks weakening participation and slowing access expansion, particularly for centers caring for more complex MA populations, counter to IOTA's equity and growth objectives.

"Sticks" may be equally or more important than "carrots." Moreover, ASN recommends that *regardless* of whether MA beneficiaries are added to CMMI's definition of a Medicare kidney transplant for IOTA (or otherwise more included in IOTA), CMMI should increase the magnitude of downside risk payments. Evidence from behavioral economics and prior CMS payment models suggests that health systems respond more strongly to downside risk than to upside opportunity. When downside exposure is minimal, participation without meaningful programmatic investment becomes a rational strategy, limiting the model's impact. Anecdotally, some IOTA participants appear to have made such calculations under current risk levels. Increasing the magnitude of downside risk—paired with appropriate risk adjustment and safeguards—may therefore be necessary to prompt broader, more substantive engagement with the model's goals.[iv],[v], [vi] Effectively reducing the per patient payment will perpetuate this attitude, especially since the payment does not take inflation into account over the duration of the model.

ASN proposes an alternative strategy to counteract the dwindling financial relevance of IOTA. ASN agrees with CMMI that transplant centers face an increasing incentive to ignore IOTA's incentives because of the shrinking FFS population. Keeping the per-FFS-transplant incentive fixed means the overall annual payment risk faced by centers will decrease year-over-year. While spreading the incentive to MA transplants is a good way to mitigate this risk, it is not the only way.

If CMMI is unable to spread the incentive to MA transplants, ASN recommends that CMMI consider an adjustment to the per-FFS-transplant (per DRG) incentive that ensures that the annual total incentive faced by transplant centers is stable across all Medicare transplants and not based on MA market penetration. Specifically, CMMI could add a multiplier to IOTA participants' payments that is linked to their traditional FFS beneficiaries but that reflects their number of MA patients as a percentage of all Medicare beneficiaries that get transplanted in a given year during the IOTA model.

> At present, if Medicare FFS transplant volume is X per year and the payment incentive an IOTA participant has earned (either upside or downside) is C, payments over the entire year are:
>
> **C * X**
>
> Year-over-year, it is apparent that as X shrinks, the total annual payments shrink.
>
> Under the proposed rule, if the MA transplant volume is Y per year, and the payments are now distributed across FFS and MA transplants, the adjusted incentive could be denoted as C' per transplant. This would result in a total annual incentive payment of:
>
> **C' * (X+Y)**
>
> This incentive is clearly more robust to the loss in FFS enrollment, since MA growth comes directly from FFS.
>
> ASN proposes modifying this approach, where CMS creates a modified per-FFS-transplant incentive that scales up C' to incorporate the MA transplant volume. That is, a modified per-FFS-transplant incentive would be C' * (X+Y)/X. Under this modification, the total annual incentive payment is equivalent to what CMMI has proposed and would mitigate concerns related to a shrinking FFS population (X):
>
> **[C' * ((X + Y) / X)] * X**

ASN notes that in the very unlikely scenario of an IOTA participant transplanting MA beneficiaries but zero FFS beneficiaries, the modifier does not calculate a value (because X is in the denominator of the modifier). A similar challenge would occur if the number of MA beneficiaries were very substantially greater than FFS beneficiaries. A solution to this challenge would be to institute a ceiling to the modifier such that it cannot create upside or downside incentives that are many orders of magnitude larger than the transplant DRG itself.

CMMI also asks for input on the "non-interference clause. This clause essentially states that CMS can't interfere with the relationship between MA plans and their contracted providers (in this instance, hospitals or health systems with kidney transplant programs). With the caveat that ASN is not offering legal advice, the society's plain-English read of this situation is that if

CMMI is awarding payments or penalties to hospitals or health systems with kidney transplant programs, an MA plan that contracts with the same hospital or health system is not involved whatsoever. Such a dynamic may be similar to pre-transplant care costs for MA beneficiaries, for which hospitals and health systems receive payments from Medicare based on cost reports they file. (Again, ASN also believes that adjustments based on performance in IOTA applied to cost report payments to IOTA participants related to MA beneficiaries may be an avenue for CMMI to explore.) The alternative payment proposal by ASN in the preceding section will be linked to FFS beneficiaries, so theoretically should not be considered "interference"

Lack of transparency and limited data availability (e.g. concerning MA plans' provider networks and prior authorization requirements) impede efforts to strengthen care for MA enrollees with kidney disease. CMMI poses numerous additional questions about how MA could play a role in the IOTA model. ASN addresses aspects of several of these inquiries, but as an overarching theme, notes that the lack of transparency and limited data availability from MA plans inhibits ASN's ability to understand or make meaningful recommendations about them. CMMI, and HHS more broadly, should urgently take steps to address this limitation for patients, researchers, and policymakers.

Anecdotal evidence suggests that MA plans do not include transplant care-related performance measures in their contracts with hospitals or any other provider type. However, there is limited visibility into MA plans' performance measures or incentives, as negotiated with in-network providers, including transplant hospitals, so evidence for this statement is exclusively anecdotal. Consequently, it is difficult to know whether any performance measure used in traditional Medicare may be aligned or misaligned with performance measures in MA. ASN advocates for greater transparency in MA plans' performance measures to avoid misalignment and, consequently, underperformance by providers relative to both payers' standards.

Similarly, there is little transparency into MA plans' prior authorization requirements, which must commonly be met before patients' transplant care will be covered. For example, while some transplant hospitals have removed requirements that their patients have a clearance from a dental care provider in order to be waitlisted or maintain active status on the waitlist, anecdotally they report that MA plans and other commercial insurance plans still impose such dental clearance requirements (without substantial evidence tying dental clearances to improved transplant-related outcomes), thereby impeding patients' transplant access.

ASN also recommends that MA plans disclose how many transplant evaluations they will cover in a year, as some plans are reported to have limited beneficiaries to just one. Greater transparency in MA plans' prior authorization requirements would help patients in selecting an MA plan that meets their transplant care goals, and it would help CMS and transplant hospitals to recognize the barriers the transplant hospitals are confronting in growing their transplant volumes, in line with CMS's goals.

While MA plans "must provide all original Medicare services to its enrollees," ASN is not aware of any network adequacy requirements that exist for access to kidney transplantation for MA plans. Anecdotally, lack of in-network transplant programs has impeded some patients' ability to access kidney transplantation or post-transplant care. However, ASN also recognizes the reality that in many regions it would be logistically and potentially financially infeasible to have traditional network adequacy requirements for access to kidney transplantation, simply because there are so few transplant centers. The existing mechanisms for establishing network adequacy are not workable when it comes to kidney transplant access and may warrant a total

redesign that addresses the needs of kidney transplant candidates and recipients without causing extensive MA market or pricing disruption.

ASN is aware that CMS permits MA plans to provide transplant care at "a distant location," farther away than the normal community patterns of care, and that it must provide reasonable transportation and accommodations.[vii] However, due to the lack of available data regarding MA beneficiaries and their care, it is unclear to what degree this flexibility is offered and accessed by patients. ASN again notes that greater transparency for patients about the transplant services an MA plan has in-network is essential to empower patients to make informed choices in their coverage that enable their care goals.

ASN notes that in the CMS-HCC risk adjustment model, which determines Medicare's capitation payments to MA plans, there are distinct adjusters for beneficiaries receiving transplant surgery and post-transplant care.[viii] While it is important for plans to be made whole with a risk adjustment model, ASN is concerned that significant disincentives to promote kidney transplantation nonetheless exist for MA plans. Given patient turnover between plans, long-term cost savings reflecting the lower cost of kidney transplant care that could accrue to the MA plan are unpredictable and may never materialize. Even recognizing that there is some risk adjustment, it is unclear to ASN whether margins for MA plans for the care of people on dialysis versus the care of people with a kidney transplant are proportional.

While realignment of payment incentives to promote transplantation for MA beneficiaries is an effort that may necessitate action beyond IOTA, ASN nonetheless encourages CMS to explore whether current arrangements are sufficient to ensure access to high-quality transplant care (and do not contain any inadvertent disincentives). The society stands ready to make its expert members available to share additional input if that would be useful in future CMS considerations.

Transparency Requirements

Evaluation criteria

ASN continues to strongly support greater transparency for patients and applauds CMMI's proposal to enhance IOTA's focus on empowering patients through information-sharing. ASN has previously commended IOTA's focus on empowering patients by making waitlist eligibility criteria publicly available and supports CMMI's proposal to also make living donor criteria publicly available.

Sharing these criteria will enable patients and potential living donors, as well as their nephrology care teams, to better understand the evaluation process and make more informed decisions regarding where to pursue transplantation or donation, leading to a more efficient and patient-centered process. Certain centers have unique expertise or the ability to accept and transplant more complex patients, yet these important differentiating factors are often not presently knowable to patients. Particularly because some patients' insurance will only cover one transplant evaluation workup annually, it is vital that patients can access information that will better enable them to select the center most likely to accept and transplant them.

ASN believes it is reasonable to require programs to update this information at least once annually. To ensure center-reported criteria are concordant with patient experiences, robust pre-waitlisting data will need to be collected on referred patients, patients who started the evaluation, and patients who completed the evaluation at each center (in addition to data now available on waitlisted patients in SRTR). The society recommends that CMS coordinate with

HRSA to ensure such data are collected and made publicly available as soon as possible to support comparisons between posted criteria and patients' transplant access outcomes.

ASN previously recommended, and continues to support, that a standard format (a template) be developed (ideally, by HRSA and the OPTN) so that all centers are presenting this information in a uniform fashion—or that the information is presented in a template via an online platform operated by HRSA or OPTN. The CMMI proposal notes that it considered proposing such a template based on suggestions from commenters (including ASN) that could include absolute contraindications, financial and insurance requirements, and psychosocial factors that impact listing decisions. ASN strongly supports this approach, as it would ensure the conveyance of important parameters and allow patients make apples-to-apples comparisons. The society also emphasizes its desire to see as much of this information developed and conveyed by HRSA or OPTN, versus creating additional burdens for local transplant centers that refocus them from patient-facing work to computer-facing work.

In addition, the society also suggests that HHS have HRSA develop (or adopt/modify an existing prototype) a platform that allows prospective patients and donors to compare programs based on these criteria as part of the OPTN Modernization Initiative. SRTR has an early version of a tool along these lines that could potentially inform such a platform, which could be piloted in IOTA, then expanded to nationwide use.

<u>Retrospective organ offer information sharing</u>
In particular, ASN remains strongly supportive of retrospective, asynchronous sharing of organ offer responses made on patients' behalf and commends CMMI for proposing to do so in the context of IOTA every six months.

As ASN has previously discussed, not every patient will want information about offers made on their behalf and it is important that a pathway exists for them to opt out of receiving it. However, many patients and their families have expressed interest in obtaining and using this information to guide future decisions made on their behalf: ASN supports fulfilling this desire. The vast majority of patients with kidney diseases (including those that that do not want this information themselves) believe that patients have a right to know this information if they so choose, as recent studies cited by CMMI overwhelmingly confirm.[ix] This belief is also consistent with CMS regulation, particularly the 2020 CMS Interoperability and Patient Access Final Rule (CMS-9115-F), which affirmed that patients have a right to access their healthcare data and information.[x]

At present, organ offers that are declined are not discussed with patients and most patients who die on the waitlist die without knowing that they were skipped over for multiple offers that went on to be successfully transplanted into other patients. People who die waiting for a kidney have received a median of 17 offers that were declined for them but were ultimately transplanted into another candidate.[xi] Between 2015 and 2022, 20.1% of patients who had received at least one offered kidney that was transplanted into another patient died waiting or were removed from the waitlist because they were too sick to transplant.[xii]

While ASN strongly supports CMMI's proposal to share organ offer information with patients retrospectively every six months and to allow patients to opt-out of receiving it, the **society does not support** CMMI's proposal to share this information only with patients who have been on the waitlist for three or more years. ASN concurs with CMMI's assessment that sharing this information will require more time and effort, particularly on the part of transplant nephrologists, and thus appreciates CMMI's intent to "balance between the operational burden for IOTA participants" with when eligible IOTA waitlist beneficiaries could start getting transplantable

offers. However, the proposed approach is misguided for several reasons, and ASN offers alternative strategies for CMMI to consider in minimizing burden.

- Patients begin receiving offers within weeks on the waitlist.[xiii]
- The longer a patient is on dialysis awaiting a transplant, the less healthy—and less able to receive a transplant—they become.

ASN and CMMI agree that sharing organ offer decline information will prompt more shared-decision making conversations between potential kidney transplant recipients and their care teams, and ideally those conversations should happen as early as possible in the patients' transplant journey, potentially shortening time on dialysis and receiving an organ that is acceptable to the patient and care team sooner.

ASN reiterates its position that offer declines should be shared with both the patient and their referring nephrologist, who can help the patient consider their care goals for future organ offers and how they would like decisions to be made on their behalf by the transplant center. This may help meet the goals of shared decision making and prompt more communication among the patient, referring nephrologist and transplant program. Again, technology should be utilized to automate the transfer of this information to the referring nephrologist.

ASN suggests CMMI consider alternative approaches the society has previously suggested to reduce burden on centers, below. The society appreciates that CMMI proposes to utilize existing OPTN refusal codes in sharing the reasons why organs were declined, a recommendation ASN previously made and continues to support, advancing operational efficiency by relying on existing data.

- **Limit organ offer information sharing to a certain point in the match run**. Based on the fact that 25% of kidneys are offered to at least 73 candidates before being accepted and successfully transplanted, ASN has suggested organ offer declines should be shared with candidates up to match run sequence 150.[xiv] Alternatively, CMMI could mirror the SRTR definition of a hard-to-place kidney (100) and cap sharing the organ offer decline information at people who were lower than 100 in the match run sequence.

- **Share only offers of organs that went on to be successfully transplanted**. While ASN appreciates the spirit of CMMI's goal to provide "more comprehensive" information, the society believes there is a tradeoff between the volume of information that would have to be conveyed, as compared to its value to the candidate. For many candidates, this trade-off is not worthwhile: ~90% of offers are generated by kidneys that ultimately are not used (discarded).[xv] Focusing the information sharing on kidneys likely to have been considered to be of sufficiently high-quality to be used in transplant surgery should appropriately limit the offer-information shared with patients.

- **Leverage technology and existing data** to minimize the work IOTA participants must do to prepare this information for patients. Automating as much of the data-sharing with patients as possible is essential to preserve transplant nephrologists' and other transplant professionals' time available for these conversations, as needed. ASN is heartened to read about collaboration between CMMI and HRSA with respect to organ offer data sharing and believes HRSA and the OPTN should develop an automated mechanism to support transplant centers in sharing this information with patients and their referring nephrologist. Much of the relevant information CMMI proposes to be

shared already exists in the OPTN database and a twice-annual report could be generated for each patient (and shared through a similar platform as described above). The creation of this infrastructure is solidly in line with the OPTN Modernization Initiative, which focuses on greater transparency, increased accountability, and adoption of 21st century technology and should be a top priority for HHS via the Next Gen contracts.

In this vein, ASN appreciates that CMMI considered proposing creating a template for programs to use to present this information, a recommendation the society has previously supported, together with the notion that as much of the existing data as possible be automatically populated into such a template. A (largely) pre-populated template that can be provided to patients may not be a substitute for a meaningful conversation about this information with a member of the transplant care team, but it would obviate the need for each program to create it and ideally minimize the need for them to populate it. Again, this could also be shared via an online platform that houses other transplant-related information (such as evaluation criteria).

Despite ASN's a) strong support for organ offer information sharing and b) objection to CMMI's proposal to initiate organ offer decline sharing at three years to limit operational burden, the society is deeply concerned about the increased demands on transplant nephrologists' time this change will require. The society has previously recommended that CMMI encourage IOTA participants to add effort and cost of the time preparing and discussing this information with patients to the cost report. In the future, the development of a billing code that reflects the time and unique complexity of these crucial conversations with patients may be warranted.

At present, many nephrologists—transplant and non-transplant alike—are not well equipped to discuss organ offers with patients. There will be a substantial learning curve, and this effort will require deliberate training and standardized scripting. Critically, script development should involve patients and patient-advocacy organizations to ensure the language reflects how patients want to receive and process this information. Even highly sophisticated patients often distill complex explanations about offer declines into simplified conclusions such as "this wasn't a good-quality organ" or "this wasn't the right organ for me." Mandating organ-offer discussions without equal attention to how those conversations are conducted could inadvertently increase confusion and erode trust in the transplant system, rather than strengthen shared decision-making.

<u>Transmission of notification to patients</u>
CMMI proposes that IOTA participants may provide information about organ offer declines to patients via patient visit, email, electronically, or via mail. ASN recommends that CMMI allow IOTA participants to make the determination regarding how the information is transmitted to patients themselves. As discussed elsewhere in this letter, the society also recommends that HRSA develop a platform as part of the Modernization Improvement effort where patients could access numerous data points and information about their care and options. Such a platform would also be a natural home for making this information available.

<u>Sharing changes in active to inactive status</u>
CMMI notes that there is currently no requirement to share changes in patients' waitlist status from active to inactive and proposes that IOTA participants must share this change with patients, including the reason why, that they cannot receive offers while inactive, and information on how the IOTA waitlist patient may become active on the waitlist again (for example, updating personal information, providing new clinical data, addressing insurance issues or other factors such as medical, psychosocial, and socioeconomic), and how to contact the center.

ASN also concurs with CMMI's observations that "internal holds," in which transplant programs temporarily pause consideration of offers for a kidney transplant candidate who is "active" on the waitlist, are misleading to patients and detrimental to the efficiency of the organ allocation system.

Sharing information on active-to-inactive transitions with patients is consistent with ASN's support for sharing other information about a patient's own care with them and ASN supports this concept. The society also validates the utility and importance of having this information from the patient's perspective. The society is, however, concerned that providing each patient with a detailed recommendation as to how they may become active on the waitlist again could be an unreimbursed cost and an additional time pressure on the IOTA participants. As with organ offer decline sharing, ASN believes this new effort may warrant the development of a billing code that reflects the time and unique complexity of conveying to patients in writing or verbally the steps needed to become active on the waitlist again.

ASN also recommends that waitlist status information be included on a HRSA or OPTN-developed patient-facing platform, allowing patients the ability to log in and check their status on the wait list without waiting for notification from the transplant center. OPTN already has access to this information and making it available to patients on-demand would make the system more patient-centered and transparent.

RFI on Pre-Transplant Access Measure

In a Request for Information (RFI), CMMI seeks comment on measures that exist to assess waitlist or transplant evaluation processes. ASN has been strongly supportive of collecting pre-waitlisting referral and evaluation data across a variety of stakeholders, to inform our understanding of gaps in access and opportunities for process improvement, including via the CMS 2728 form (dialysis organizations) and through the OPTN (transplant centers). At present, due in part to the lack of available nationwide pre-waitlist data, and also due in part to the emphasis on short-term post-transplant performance metrics, ASN believes transplant centers have insufficient motivation or information (about their own performance or national performance) to improve their pre-transplant processes. More broadly, the current U.S. system does not have a thorough national understanding of current gaps in pre-transplant care to effect system change and improve this aspect of access to the optimal therapy for kidney failure.

Previously, ASN has been supportive of focusing the IOTA model on access to kidney transplantation and outcomes for people who are already on the waitlist. While ASN believes that processes of care and access to transplantation for people who are not yet waitlisted can and should improve, the society also believes the IOTA model is already testing a robust set of incentives for behavior change. The society supports the development of mechanisms to quantify pre-waitlist access but is not adamant that IOTA is necessarily the venue to test them.

Below, ASN offers perspective on many of the questions CMMI poses in the RFI (in italics), and the society hopes these insights help to inform CMMI's thinking on this important aspect of access to kidney transplantation.

Why is a quality measure that looks at access to waitlist and pre-transplantation processes important to include?

Transplantation is the optimal therapy for most people with kidney failure, and gaining access to the waitlist is a critical gateway step in the process. However, our understanding of how and

why some people make it to the waitlist and others do not is limited—restricting our ability to improve access to transplantation through either national policy or local practice changes. Nationwide, more than 500,000 people are living with kidney failure on dialysis, but fewer than one-fifth of them are actively on the transplant waitlist. The rates at which patients are referred or drop off at various stages before making it to the waitlist are unknown, as there are no national data regarding these care steps.

The first issue is that individuals with kidney failure deserve access to transplant evaluation. Access to a "fair" evaluation process is a right. Hence, it needs to be afforded to 100% of patients unless they are unable to participate in the evaluation process (such as a bed-bound nursing home patient). A quality measure(s) focused on access to the waitlist and pre-transplant processes is essential because current transplant quality measurement begins too late, leaving referral, evaluation, and progression to waitlisting largely unmeasured despite being the primary gateways to transplantation. Standardized measurement of these early steps would illuminate wide variation and inequities, enable benchmarking and targeted quality improvement, and strengthen equitable access to transplantation without serving as a punitive performance metric.

A second issue is the importance of getting waitlisted. Most evaluated candidates don't make it to the waitlist. This attrition reflects not only medical contraindications, but also variation in communication practices, evaluation workflows, weight and consideration given to financial and psychosocial factors, and clinical decision-making across transplant centers. These pre-waitlist processes represent a critical—and currently unmeasured—opportunity for quality improvement. Importantly, many of the most common reasons for waitlist denial or delay, such as social barriers, frailty, and deconditioning, are complex but not immutable.

While these factors are challenging to quantify and standardize, their frequent use as exclusion criteria underscores the need for greater transparency and consistency in how they are assessed and addressed. Comparing centers on evaluation-to-waitlist progression, adjusted for patient characteristics, would help identify best practices in patient preparation, multidisciplinary decision-making, and supportive interventions—shifting the focus from who is excluded to how more patients can be safely and appropriately supported to reach the waitlist.

Data from four U.S. regions show substantial variation in access to each transplant step among transplant centers. For example, over the time period from 2015-2023, the proportion of patients who start the evaluation after referral ranges from 1.8% to 77.7%, and waitlisting within 6 months of evaluation start ranged from 10.1% to 64.4% among 37 U.S. transplant centers. Variation also exists in time between each step. Median time from dialysis start to transplant referral was 7.8 months (range: 0 to 118.5 months). Median time from referral to evaluation start was 2.0 months (range: 0 to >100 months). Median time from evaluation start to waitlisting was 6.9 months (range: 0 to >100 months).[xvi] Research shows that discrepancies in early steps along the path to transplantation—such as referral and waitlisting—are influenced by multiple factors, including geographic location, insurance status, age, and other characteristics.[xvii]

Studies demonstrate that many people with kidney failure who would benefit from transplantation from a clinical standpoint do not make it to the waitlist. For example, one study demonstrated that less than half of people under age 40 on dialysis with no other major comorbidities were listed for a kidney transplant within 5 years of initiating dialysis (and just 30% had been added to the waitlist within 1 year of dialysis initiation), indicating major barriers in access to optimal care even in the absence of poor health status or medical contraindications to transplantation.[xviii,xix,xx,xxi,xxii] The 2022 National Academies of Science, Engineering, and Medicine (NASEM) report on the transplant system highlighted the lack of reliable data on the

number of patients who enter the transplant pathway (e.g., patients who might benefit from referral and transplant evaluation). The report also went on to explain that there are few—if any—ways to properly assess the effect of socioeconomic status on transplant access in particular and recommended collecting this data to identify and ameliorate areas of wide variation.[xxiii]

The available literature illustrates that transplant centers' behaviors, processes, and decision-making structures in the context of evaluations and waitlisting are highly variable across transplant centers.[xxiv, xxv, xxvi, xxvii, xxviii] Because of this variation and because of the importance of these early, pre-transplant care steps for supporting patients' passage through to receiving a transplant, having robust measures capturing information about hospitals' waitlist or transplant evaluation processes, how they vary, and how they influence patients' transplant access outcomes downstream would be valuable in informing interventions to standardize, streamline, and strengthen transplant operations and improve patients' outcomes.ASN has, and continues to, envision the collection of this data as informing benchmarking for quality improvement efforts—not as the basis of a public performance metric with rigid performance expectations or payment implications.

What existing measures are being used to measure access to the waitlist or transplantation evaluation processes?

While no set of measures about these processes or related factors have been widely used for transplant centers, several studies have developed and used measures of patient-level transplant access outcomes throughout the transplant care pathway, including studies cited in CMS's proposed rule. The measures developed in these studies capture patients' progression through evaluation and waitlisting stages of the pre-transplant care process including the percent of patients reaching each step of the pre-transplant pathway: referral, evaluation start, and waitlisting.[xxix,xxx,xxxi]

Assessing the performance of measures on referral and evaluation start outcomes has been enabled by the development of the multi-regional E-STAR database which includes data from 37 transplant centers across 13 states.[xxxii] Quality measures for waitlisting access have been developed based on regional data, but have not been widely used due to lack of pre-waitlisting data collection.[xxxiii] For example, a standardized waitlisting rate, defined as the ratio of patients who are waitlisted in a center relative to the person-years referred for evaluation to a program, was developed and examined among Southeastern transplant centers.

When measuring pre-transplantation processes, what specific components should be analyzed (for example, time from referral to waitlist, time from waitlist to transplant)?

Historically, transplant-focused performance measures have focused on steps of care between waitlisting and transplant. But by this point, many patients pursuing a transplant who could be considered good candidates have already leaked out of the pipeline. A comprehensive measure set, then, would capture all pre-transplant care processes, including 1) referral, 2) starting the transplant evaluation, 3) completing the transplant evaluation (such that would allow for the transplant center to make a waitlisting decision), 4) waitlisting, and potentially even 5) waitlist maintenance (including maintaining active status and avoiding delisting). With an increasingly older and medically complex population with kidney failure being waitlisted in an era of lengthening wait times, keeping patients ready for transplant is an underappreciated but enormous challenge for transplant centers and a strained transplant nephrology workforce.

The denominator for each of these measures is important. For example, to specifically target transplant center-focused behaviors, a measure for waitlisting could consider the "at risk" denominator of patients who were on dialysis, referred, started the evaluation, or completed the evaluation:

- If the measure examines waitlisting among all dialysis patients, this would capture both dialysis facility and transplant center processes.
- If the measure focused on referral to waitlisting, it would largely capture transplant center processes such as outreach behaviors, closed referral procedures, etc.
- If the measure focused on evaluation start to waitlisting, then the specific processes and procedures for the evaluation process could be captured.

ASN recommends multiple measures for this purpose, including a measure that examines referral among those that started dialysis, evaluation start among those that were referred, evaluation completion among those that started the evaluation, and waitlisting among those that completed the evaluation. The time between each step (and time spent in active vs inactive waitlist status) also should be examined, as this could be used to observe variation, improve system efficiency and drive quality improvement.

ASN also notes that education at or after the time of a kidney failure diagnosis is an important component for consideration, although since this effort falls primarily to dialysis organizations and general nephrologists, it would not likely be appropriate for IOTA. (It could be worth considering whether a future model should establish shared responsibility for outcomes for people with kidney failure among community nephrologists, dialysis organizations, and transplant centers—including transplant nephrologists.)

ASN reiterates that it is recommending development of mechanisms to inform benchmarking and performance improvement, not for payment purposes.

What data would be necessary to create measures of time from referral to waitlist and time from waitlist to transplant?
How could that data be transmitted to CMS in a way that minimizes burden to transplant hospitals?

ASN believes the data needed to create measures could be derived from the existing E-STAR database for exploration to develop quality measures; however, these data are limited to 37 transplant centers, and national data collection (from HRSA) is needed for measures to be validated and then utilized in IOTA. The data that will be made available forthcoming from the revised CMS 2728 form (which includes information about transplant education, referrals, and related reasoning) is helpful (though ASN notes that these data would miss up to 20% of referrals for transplant that are "preemptive," or occur prior to when a patient starts dialysis). Ideally, the HRSA pre-waitlisting data collection effort (as required by a February 2024 HHS directive and most recently promulgated as OMB 0906-xxxx-New) should ideally suffice.

ASN notes that it is unknown whether numerous recommendations the society has made to ensure the HRSA data collection efforts are comprehensive, minimally burdensome (including using batch submission), accurate, and appropriately monitored/audited to ensure quality. These considerations are essential to fully execute the HHS directive. If implemented robustly, these two nascent data collection efforts (CMS 2728 and HRSA/OPTN pre-waitlisting data collection) should be sufficient for any future pre-waitlisting quality measurement efforts, and IOTA could

consider testing pre-waitlisting quality measures using these data in future years once these data are collected.

ASN does not believe any additional data collection efforts (such as efforts led by CMS) are needed or would be appropriate, as they would be duplicative, uninformative, and likely add unnecessary burden for transplant centers. CMS and HRSA should work together to share this data amongst their agencies. The society has previously stressed the importance of enabling bidirectional communication between the pre-waitlisting data collected by HRSA/OPTN and CMS. Making these two datasets compatible and linkable is essential to create a complete picture of the patient journey and identify barriers that can be overcome through future policy or practice changes.

As discussed in the previous section, keeping this population ready for transplant is a major undertaking especially for older, highly comorbid patients. This challenge is compounded by the fact dialysis care and waitlist care are siloed from one another. It may be helpful if CMS could organize claims data to inform transplant centers when listed beneficiaries have been recently/are hospitalized (since neither patients nor referring physicians notify transplant centers). Interoperability between the sites where kidney transplant candidates receive care would substantially help, too.

In this vein, ASN also notes a role for EMR vendors in making available the pre-waitlisting data CMS would need. Having all EMRs use the same data standards and elements is needed to eliminate some of the variation in terms and definitions (and to enable the previously mentioned batch submission). ASN urges HHS to support the development and adoption of a standardized data dictionary/common data model for transplant nephrology (and all solid organ transplantation), together with key stakeholders in the community, CMS, CMMI, and HRSA/OPTN, such as through the Assistant Secretary for Technology Policy.

Allocation Out-of-Sequence

CMMI invites additional input on how it should address allocation out of sequence (AOOS) in IOTA, building on feedback it received in the first round of IOTA rulemaking. While ASN has been pleased to see AOOS decreasing in recent months, if CMMI does nothing to address the practice in the model, it may de facto reward participants for continuing to violate the match run.

The match run algorithm exists to create as objective and fair access as possible to available kidneys. In contrast, AOOS relies on relationships between a given organ procurement organization (OPO) and a transplant center, introducing more subjectivity and the possibility of lesser access to kidneys for patients who are at transplant centers that lack those relationships. Once centers have accepted an AOOS kidney, they have latitude to then give it to any patient on their waitlist.

It is important to note that in the past, AOOS kidneys were much more “marginal,” in contrast to today’s reality, in which many AOOS kidneys transplanted are moderate quality organs that do not meet the traditional definition of “hard to place.” As AOOS has grown, now accounting for approximately 20% of all kidneys, discard rates have *also* grown, despite a popular belief that AOOS “saves” kidneys that would have otherwise gone unused. Notably, recent data suggest that AOOS is being used earlier and earlier in the match run.[xxxiv]

AOOS as previously (and in some instances, currently) implemented, is inconsistent with evidence-based allocation principles and should be discontinued where it persists. However, the

society supports the development of formal, standardized, and transparent expedited allocation pathways within the OPTN framework to facilitate timely placement of kidneys at highest risk of nonuse. Ideally, this mechanism could be put in place on a temporary basis within the existing allocation framework as a new, improved allocation framework supported by 21st century technology is developed.

In the meantime, CMMI requests input as to whether AOOS kidneys should be included or excluded in calculations of IOTA participants' performance in the Efficiency and Achievement Domains. Emerging data suggest that inclusion of AOOS kidneys meaningfully alters Efficiency and Achievement Domain scores for a substantial proportion of transplant centers under both the finalized Performance Year (PY) 1 scoring framework and the proposed PY2 framework, resulting in measurable reclassification across performance thresholds, as compared to what those scores would have been if AOOS kidneys were excluded. These scoring changes translate into nontrivial shifts in potential upside payments in PY1, with larger and more heterogeneous financial effects observed under the proposed two-sided risk structure in PY 2.

For example, in this policy simulation model, when AOOS kidneys were excluded, more than 25% of IOTA participants experienced a change in their Efficiency Domain score, equivalent to changes in upside payments ranging from approximately -$170,000 to more than +$275,000, as compared to what payments would have been had AOOS kidneys been included. In PY2, when downside payments are introduced, excluding AOOS kidneys changed upside payments ranging from approximately -$215,000 to nearly +$500,000 and downside payments ranging from approximately -$30,000 to more than +$65,000. This model highlights the significant effects that including AOOS kidneys in IOTA performance domain calculations may have on IOTA participants' consideration of accepting AOOS kidneys.

Inclusion of AOOS kidneys in the Efficiency Domain is likely to advantage centers that accept more of them. Because placement of AOOS kidneys is driven by OPOs offering kidneys to transplant programs whose acceptance patterns they understand (and can predict will be likely to say "yes" to a given organ), the organ offer acceptance rate ratios of programs that accept them routinely will look better than if the program only accepted organs through the match run process (which would likely involve fewer "yes" responses).

CMMI also requests input as to whether AOOS kidneys should count in the baseline years. Studies underway suggest that only 10-15 IOTA participants, which are among the most predominant users of AOOS kidneys (such as 50-70 AOOS transplants a year), would see their baseline average meaningfully decrease if CMMI were to remove AOOS kidneys from baseline performance calculations. Decreasing these participants' baseline average would make it easier for them to do well during IOTA performance years. A key objective of IOTA is to incentivize participants to invest in infrastructure and processes that enable it to increase the number of kidney transplants it can perform. If a center already had the capability to perform a greater number of kidney transplants than its baseline setting, IOTA is unlikely to have the desired change effect at that transplant program.

IOTA participants who successfully transplant waitlisted patients using AOOS kidneys likely (and to some degree, understandably) feel they deserve credit for delivering a successful outcome to a patient in the context of IOTA. At the same time, giving credit for a kidney transplant that necessitated a violation of existing OPTN rules seems antithetical in the context of IOTA, a program designed to increase access to kidney transplantation for every waitlisted beneficiary—not just beneficiaries at programs that engage in AOOS.

ASN offers CMMI three approaches to consider for addressing these issues:

Option 1: This option would be the most stringent approach to AOOS kidneys.

- Including AOOS transplants in the baseline years.
- Excluding AOOS transplants from all performance metrics (Achievement, Quality and Efficiency Domains).

Option 2: This option would give credit for AOOS transplants in the Achievement Domain while holding IOTA participants accountable for long-term outcomes of AOOS transplants in the Quality Domain.

- Including AOOS transplants in the baseline years.
- Including AOOS transplants in the Achievement and Quality Domains.
- Excluding AOOS transplants from the Efficiency Domains.

Option 3: This option would give partial credit for AOOS transplants that do not meet the traditional definition of "hard to place."

- Including AOOS transplants in the baseline years.
- Including AOOS transplant in the Achievement Domains:
    - Half credit for AOOS transplants that do not meet traditional "hard to place" criteria
    - Full credit for AOOS transplants that meet traditional "hard to place" criteria
- Including all AOOS transplants in the Quality Domain.
- Excluding AOOS transplants from the Efficiency Domains.

With option three, over time, a few years into the model, CMMI could consider reducing half-credit for AOOS kidneys that were not "hard to place" to a lower amount, or to zero.

In addition to asking CMMI to consider these options, the society supports notifying the patients who would have otherwise received *the next offer* in the match run for kidneys that were instead diverted (AOOS) to a recipient who was lower in the match run (e.g., to the one patient that would have been next, not to all the patients between the next on the match run and the recipient). This approach balances the value of transparency for patients whose care may have been substantially different were AOOS not utilized without creating an unrealistic perception amongst many patients that were skipped over that they had a strong likelihood of receiving the offer. ASN also recommends that IOTA participants that transplant AOOS kidneys submit a report to CMMI and HRSA as to why they selected the patient they did, which could potentially also be shared with the skipped patient.

Conclusion

Lastly, ASN notes that many of the recommendations it has shared in this letter for IOTA are also goals ASN maintains for the broader U.S. transplant system, including but not limited to adopting the transparency requirements, recognizing the value of transplant nephrology care, achieving interoperability between entities caring for people with kidney diseases and kidney failure, establishing steps to transparency in MA plans, creating pre-transplant access measure(s) for quality improvement, and minimizing AOOS.

Again, ASN commends CMMI for its leadership on the IOTA model, and the society stands ready to continue to provide additional information or to offer access to its expert members as CMMI considers these comments or future improvements to the model. Please contact ASN Strategic Policy Advisor to the CEO Rachel Meyer at rmeyer@asn-online.org to discuss this letter or the IOTA model more generally with ASN.

Sincerely,

Samir M. Parikh, MD, FASN
President

---

[i] Ngyuen, K et al. Medicare Advantage Enrollment Following the 21st Century Cures Act in Adults With End-Stage Renal Disease. JAMA Network Open. September 2024. doi:10.1001/jamanetworkopen.2024.32772

[ii] Adler JT et al. Implications of Increased Medicare Advantage Enrollment for Access to Kidney Transplant Waitlisting JASN 36: 1173–1175, 2025. doi: https://doi.org/10.1681/ASN.0000000667

[iii] Adler JT et al. Implications of Increased Medicare Advantage Enrollment for Access to Kidney Transplant Waitlisting JASN 36: 1173–1175, 2025. doi: https://doi.org/10.1681/ASN.0000000667

[iv] Mohan S., et al. Center behavior and location, and its impact on transplant disparities. AJT. November 2025.

[v] Sharif A. Risk Aversion, Organ Utilization and Changing Behavior. Transpl Int. April 2022. doi: 10.3389/ti.2022.10339

[vi] Mehrotra A, Sorbero ME, Damberg CL. Using the lessons of behavioral economics to design more effective pay-for-performance programs. Am J Manag Care. 2010 Jul;16(7):497-503. PMID: 20645665; PMCID: PMC3303871

[vii] Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections. April 22, 2016. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf

[viii] Information on 2023 CMS-HCC ESRD Risk Adjustment Model and Updates to Monthly Membership (MMR) and Model Output Reports (MORs). October 4, 2024. https://www.cms.gov/files/document/2023esrdmodelmorandmmrupdates508g.pdf

[ix] Husain SA et al. Patient and Provider Attitudes Toward Patient-Facing Kidney Organ Offer Reporting. Kidney International Reports, Volume 10, Issue 4, 1122 - 1130

[x] Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Interoperability and Patient Access Final Rule (CMS-9115-F). May 20, 2020. Federal Register 2020-05050 (85 FR 25510). https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and

[xi] Husain S et al. Association Between Declined Deceased Donor Kidney Offers and Candidate Outcomes JAMA Network Open. 2019;2(8):e1910312. doi:10.1001/jamanetworkopen.2019.10312

[xii] Yu M., Maclay L., Husain S., Schold J., Mohan S. Deaths on the Waitlist Following Declined Offers Represent Missed Opportunities for Patients, American Transplant Congress, June 1-5, 2024, Abstract A 107

[xiii] Husain SA et al. Association Between Declined Deceased Donor Kidney Offers and Candidate Outcomes JAMA Network Open. 2019;2(8):e1910312. doi:10.1001/jamanetworkopen.2019.10312

[xiv] Ibid.

[xv] Yu M., Maclay L., Husain S., Schold J., Mohan S. Deaths on the Waitlist Following Declined Offers Represent Missed Opportunities for Patients, American Transplant Congress, June 1-5, 2024, Abstract A 107

[xvi] E-STAR Dashboard. https://estardashboard.shinyapps.io/public/

[xvii] Paul S. et al. Kidney transplant program waitlisting rate as a metric to assess transplant access. Feb. 2020. AJT.

[xviii] Husain S et al. Disparities in Kidney Transplant Waitlisting Among Young Patients Without Medical Comorbidities JAMA Intern Med. doi:10.1001/jamainternmed.2023.5013
[xix] Wadhwani S et al. Medical Need, Financial Resources, and Transplant Accessibility. JAMA. 2022;327(15):1445-1446. doi:10.1001/jama.2022.5283
[xx] Dubay D et al. Insurance Type and Solid Organ Transplant Outcomes. J Am Coll Surg. 2016 Oct; 223(4): 611–620.e4
[xxi] Schold S et al. Failure to Advance Access to Kidney Transplantation over Two Decades in the United States. JASN April 2021. doi: 10.1681/ASN.2020060888
[xxii] Axelrod D et al. The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Area Travel on Kidney Transplant Access and Outcomes. CJASN December 2010. DOI: 10.2215/CJN.04940610
[xxiii] National Academies of Sciences, Engineering, and Medicine. 2022. Realizing the promise of equity in the organ transplantation system. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.
[xxiv] Smedley B. et al. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Institute of Medicine. National Academies Press. 2003.
[xxv] Brady, J. et al. AHRQs National Healthcare Quality and Disparities Reports: An Ever-Expanding Road Map for Improvement. Health Serv Res. June 2007.
[xxvi] Urbanski, M. et al. Body Mass Index as a Patient Selection Criterion for Kidney Transplant. Common Health. 2020.
[xxvii] Rodrigue, J. Biopsychosocial Perspectives on Transplantation. 2001.
[xxviii] Urbanski, M. et al. Transplant Professionals' Perceptions of Long-Term Care Residents' Candidacy for Kidney Transplantation. Prog Transplant. 2017 Jun;27(2):146-151. doi: 10.1177/1526924817699968
[xxix] Patzer RE et al. A Randomized Trial to Reduce Disparities in Referral for Transplant Evaluation. JASN. March 2017. *DOI:* 10.1681/ASN.2016030320
[xxx] Patzer RE et al. A Culturally Sensitive Web-based Intervention to Improve Living Donor Kidney Transplant Among African Americans. Kidney Int. September 2019. https://doi.org/10.1016/j.ekir.2019.05.771
[xxxi]Patzer RE et al. The ASCENT Intervention to Improve Access and Reduce Racial Inequalities in Kidney Waitlisting: A Randomized, Effectiveness-Implementation Trial. CJASN. March 2023. DOI: 10.2215/CJN.0000000000000071
[xxxii] E-STAR Dashboard. https://estardashboard.shinyapps.io/public/
[xxxiii] Sudeshna, P. et al. Kidney transplant program waitlisting rate as a metric to assess transplant access. Am J Transplant. 2021 Jan;21(1):314-321.doi: 10.1111/ajt.16277
[xxxiv] Husain SA et al. Expedited kidney offers are occurring earlier during allocation. Kidney Medicine. *Accepted* February 2026.