



July 16, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases, the nearly 90,000 individuals awaiting a kidney transplant, and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed Increasing Organ Transplant Access (IOTA) Model, which aims to increase access to life-saving transplants for patients living with kidney diseases and reduce Medicare expenditures.

ASN commends the Center for Medicare and Medicaid Innovation (CMMI) for its long-standing commitment to developing and testing models to improve care and outcomes for millions of individuals experiencing kidney diseases. ASN's members, both general and transplant nephrologists, are on the frontlines of kidney care with their patients and along with the other essential members of kidney care teams. The society concurs with CMMI that "[k]idney transplantation is the best treatment for most patients with chronic kidney disease and end-stage renal disease, but there are more people in need of a kidney than there are organs available. Many people die while waiting for a kidney transplant."

A successful kidney transplant is a gift of incalculable value to a person with kidney failure. While ASN's comments on recommendations for improvement of the IOTA Model will address various aspects of costs savings and measurement of quality and outcomes, it is important to bear in mind that a successful kidney transplant gives a person a chance to live free of dialysis while also increasing life years and overall quality of life. Accordingly, maximizing patient access to the optimal form of therapy for kidney failure, transplantation, has long been a top policy and advocacy goal for ASN. In recent years, the society has advocated for a new payment model to test mechanisms of supporting and incentivizing greater access to kidney transplants, and to expand that access to populations that have historically had lower rates of kidney transplantation. ASN commends CMMI for its time, effort, and commitment to this tremendously important cause.

ASN supports CMMI's efforts, with recommendations for improvement found in this letter, and the four goals of the model:

- Increase number of, and access to, kidney transplants.
- Improve utilization of available deceased donor organs.

- Support more donors through the living donation process.
- Improve quality of care and equity

These goals align with ASN's top policy priorities:

- Intervene earlier to prevent, diagnose, coordinate care, and educate
- Transform transplant and increase access to donor kidneys
- Accelerate innovation and expand patient choice
- Achieve equity and eliminate disparities
- Bolster the kidney health workforce

ASN appreciates CMMI's emphasis on successful achievement of a transplant itself as a major focus in this proposed model and agrees this ultimate outcome is an appropriate goal upon which to place significant attention. As a matter of principle, ASN also appreciates the simplicity of this model design. ASN offers detailed comments in the letter below and the society's key recommendations are as follows:

1. Set performance targets at realistically attainable thresholds for IOTA participants.
 - a. As proposed, assuming just a 5% national growth rate, a baseline 100-transplant program that achieved 150% growth (e.g. the top tier) annually would by year six be transplanting more than 1,500 patients per year. In that six years it would have performed a total of 3,193 transplants (Appendix 1 Table B, line 18)—more than CMMI forecasts *all* IOTA participants would generate combined during the same six years (2,625 additional transplants). Therefore, instead of incentivizing the exponential growth per year as proposed, ASN recommends incentivizing growth above the national growth rate *itself* and
 - b. Stratifying into three national growth rate targets by kidney transplant program volume.
2. Increase the scale of the incentives to ensure the model is sufficiently powered to attract attention and investment in kidney transplant programs, which will be crucial to enable achievement of IOTA's goals. Specifically, ASN recommends a \$15,125 upside risk maximum and a \$3,750 downside risk maximum.
3. Affirm that pre-transplant costs associated with IOTA, such as additional resources needed to maintain an active waitlist and provide additional support for patients to complete their evaluation, would be covered through the Organ Acquisition Cost Center (OACC)
4. Shift 10 points from the Achievement domain to the composite graft survival rate component of the Quality domain, reflecting the importance of ensuring successful long-term outcomes as well as increasing transplant rates
5. Finalize the proposed 1.2x health equity payment adjustment multiplier in the Achievement domain, which helps address well-documented barriers to transplant for socioeconomically disadvantaged patients, and consider using additional multipliers to encourage IOTA participants to make gains on other key goals:
 - a. Apply the 1.2x multiplier to the Quality domain, encouraging focus on long-term outcomes of eligible patient populations
 - b. Add a multiplier for use of "hard-to-place" kidneys, which are likely to accrue more cold ischemia time and experience delayed graft function regardless of organ quality

- c. Add a multiplier for pre-emptive transplantation, scaled to reflect the substantial savings to the Medicare program that pre-emptive transplants confer relative to maintenance dialysis
6. Support and expand the proposed waivers and patient engagement incentives, but identify a source of funding to support IOTA participants in conducting these efforts
7. Revisit the overall savings assumptions and calculations for the model, which ASN believes are undervalued

One of the most significant challenges to accomplishing ASN's and CMMI's shared goal of maximizing patient access to kidney transplantation is the shortage of transplant nephrologists and other transplant professionals—a shortage that, ironically, will worsen as the shared goal of increasing transplant rates is attained. Currently, there are more than 250,000 patients with a functioning kidney allograft and approximately 90,000 waitlisted patients awaiting kidney transplants, with a burgeoning number added to the kidney transplant waitlist every year. It is estimated that there are additionally tens of thousands of patients with advanced kidney diseases currently in referral or still undergoing evaluation for a transplant who are not yet on the waiting list. In 2022, more than 40,000 patients were added to the kidney waitlist and more than 25,000 received a kidney transplant.

While IOTA is a model primarily aimed at transplant hospitals, transplant nephrologists are primarily responsible for the care of patients both in the pre- and post-transplant phases. Thus, the burden of the work would fall disproportionately on transplant nephrologists, already facing a workforce shortage. While the transplant nephrology workforce is critical to success in IOTA, it is not the only resource that needs to be increased. Hospitals and health systems will have to be willing to provide access to operating rooms, hospital beds, as well as clinic space.

While fully supporting IOTA's goals, ASN recommends a less aggressive set of expectations for growth in the transplant rate throughout this comment letter, informed in part by the reality that the supply of professionals who are integral to providing transplant care is, regrettably, severely limited.

1. **CMMI seeks comment on its proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during the baseline years, and the exclusion of pediatric-only centers.**

ASN supports the recommendation to exclude programs that perform fewer than 11 kidney transplants and pediatric kidney transplant centers. As discussed later, ASN notes that centers that perform 11-50 transplants are very different from those that do 200-250 in terms of resources, capacity and growth opportunities.

ASN also supports limiting the model to kidney or kidney-pancreas transplants. However, the society seeks clarification that safety net kidney transplants would still be counted as kidney transplantations in one year after a liver, heart, and/or lung transplants given that these patients require at least the same, if not greater level of effort to achieve a successful transplant. ASN supports the inclusion of these kidney transplants. ASN also concurs that CMMI should avoid setting thresholds that will constrict participation unnecessarily and that might result in unintended consequences.

2. CMMI seeks comment on the proposed model performance period of 6 years and the proposed model start date of January 1, 2025.

ASN supports a model performance period of six years.

ASN proposes reconsideration for the three-month notice window. The society wishes to see as many IOTA participants succeed to the greatest extent possible in the model. The changes that many programs will need to institute to achieve the kinds of gains that CMMI is looking to incentivize are substantial, such as investments in workforce and infrastructure. It's not just the kidney transplant program that will have to adapt to succeed in IOTA: there are lots of other moving pieces in a hospital or health system that will need to be aligned to successfully achieve the goals of the model and that process will require time and resources. Smaller programs, in particular, might struggle to muster the resources needed to begin to make meaningful interventions on a short time horizon. A short notice period, such as the proposed three-month notice window, could also make it difficult for smaller programs to gather resources. With many hospitals and programs setting their budgets for 2025 now, adjusting to these new priorities may require more time to prepare. ASN recommends that CMMI provide a longer window of notice of participation, such as six months. Depending on when the proposed IOTA rule is finalized, a July 1, 2025, start date may be more appropriate to ensure greater participants' success.

This six-month recommendation is also informed by the kidney community's recent experience with the Kidney Care Choices (KCC) and ESRD Treatment Choices (ETC) models. CKCC participants, particularly the Kidney Care First (KCF) model participants that tended to be smaller entities, struggled to have enough time to prepare their practices for success in a model they entered voluntarily. In contrast, the start date of the mandatory ETC model was moved back due to COVID-19, and participants benefitted from having more time to organize themselves. Similarly, looking back to when the newest kidney allocation policy kidney allocation system 250 (KAS250) broadened geographic distribution took effect, the system overall struggled to adjust and expand capacity to handle the increased offer volume. ASN firmly believes that the more time CMMI can give IOTA participants and the hospital and health systems in which they exist to prepare, the greater the likelihood of success.

ASN considered suggesting that CMMI attempt to start the model to align with the fiscal year. For programs that operate on a July 1 fiscal year, a July 1 start date could align well with the budgetary decision-making calendar, facilitating investments in the kidney transplant program to support success in IOTA. However, ASN recognizes that different centers operate on different budgetary timelines and thinks it would be nearly impossible for CMMI to pick a start date that aligns with every program's fiscal year.

3. CMMI seeks public comment on its proposal that the IOTA Model participants would be kidney transplant hospitals and whether it should be mandatory.

ASN supports kidney transplant hospitals as participants in IOTA for the reasons CMMI outlines in the proposed rule. As described later, ASN also supports nephrologists, nephrology practices, and dialysis facilities as potential IOTA collaborators. Particularly for nephrologists, nephrology practices, and dialysis facilities participating in ongoing CMMI kidney care models, such as the Comprehensive Kidney Care Choices (CKCC) pathway in the KCC voluntary model and ETC mandatory model, collaboration with IOTA participants could align favorably to facilitate kidney patient access to transplantation in new ways. ASN also supports that the model be mandatory to effect the systemic improvements envisioned in the IOTA model.

4. CMMI seeks comment on the proposed approach for selecting IOTA participants.

ASN appreciates CMMI's delineating the rationale behind the proposed approach selecting IOTA participants using Census Divisions, Donor Service Areas (DSAs), and kidney transplant volume. ASN agrees that it is important to ensure randomization across participants in IOTA and not in IOTA, including by examining program volume size. However, since DSAs are no longer a unit in the allocation algorithms, stratifying by DSA may make less sense today than it once would have, prior to the KAS revision implementing broader geographic sharing. Further, ASN does not believe that randomizing some centers in a geographic area and not others would create a significant challenge if the model were restricted to organs allocated within the rules of the objective allocation system given that center density and competition have not historically directly influenced center level behavior. (Husain S et al. Association of transplant center market concentration and local organ availability with deceased donor kidney utilization Am J Transplant. 2022 Jun;22(6):1603-1613.)

Instead, CMMI should consider randomizing at the transplant center level. ASN suggests that CMMI use a similar stratification approach without the DSA element, stratifying centers into two groups of lower-volume and higher-volume centers, or into three groups of lower, medium, and higher-volume centers. The goal should be a streamlined approach to comparing and evaluating centers with common factors such as size. In other words, apples to apples and oranges to oranges.

5. CMMI seeks public comment on its proposals to include all adult kidney transplant waitlist patients, regardless of payer type and waitlist status, who are alive, and registered on a waitlist to an IOTA participant. CMS also seeks comment on using transplanted patients who are similarly attributed to IOTA participants for the purposes of scoring and determining performance-based payments. CMS also seeks comment on IOTA waitlisted patients, allowing multiple attributions for multi-listed patients, and attribution/de-attribution criteria.

ASN strongly supports CMMI's proposal to include all adult kidney transplant waitlist patients, regardless of payer type and waitlist status, who are alive, and registered on a waitlist of an IOTA participant. This approach will ensure the greatest number of participants can benefit from the patient-centered changes IOTA encourages while also ensuring that centers can focus on increasing transplant volume without creating differential pathways or processes for different patient groups. ASN also supports multiple attributions for multi-listed patients, allowing whichever center a multi-listed patient ultimately receives a transplant from to receive credit for that successful outcome.

ASN understands that, at present, statutory requirements prevent CMMI from adjusting payments based on performance in IOTA for patients who have Medicare Advantage (MA) plans without a waiver and that CMMI had concerns about "the implications for such a potential waiver. However, given the significant (greater than 50%) uptake of MA plans by people who have kidney failure as compared to traditional fee-for-service (FFS) Medicare, this current reality limits the magnitude of the effect IOTA can have at any given transplant center. For example, at a center that performs approximately 200 kidney transplants annually, 60% of patients are likely to have private insurance, and roughly half of the remaining beneficiaries will now be enrolled in MA plans—leaving the payments related to the care of just 50-60 patients eligible to be adjusted up or down based on performance in IOTA (SRTR Annual Data Report 2023, Table 6).

Elsewhere in this letter, ASN offers suggestions for how to scale the performance incentives themselves to be more meaningful, but ASN observes that having just one-quarter of patients' payments eligible for adjustment is going to inherently limit the model's ability to command the attention of decisionmakers in a hospital or health system to support changes that ensure success in the model. As such, ASN suggests that CMMI explore every possible avenue working with Congress to identify waivers for SSA 1851(i)(2) to allow payments related to the care of both FFS and MA patients be subject to adjustment in IOTA.

CMMI could also potentially approach including the MA patient population in the model by applying an upside incentive to Organ Acquisition Costs that Medicare covers for MA beneficiaries who receive a transplant (and potentially FFS beneficiaries as well). Such an approach could more directly encourage focus on increasing transplant rates among the MA patient population than just including them in the calculation of the performance score that mediates payments to traditional FFS Medicare patients exclusively.

ASN requests that CMMI affirm that pre-transplant costs associated with IOTA, such as additional resources needed to maintain an active waitlist and provide additional support for patients to complete their evaluation, would be covered.

For patients who are de-attributed from IOTA due to graft loss or death, ASN inquires what source of data CMMI will use to verify graft loss or death. Recent findings regarding the substantial variation between national kidney registries regarding graft loss and death underscore the importance of ensuring the accuracy of the data sources used in this mandatory model. (Yu M et al. Discrepant Outcomes between National Kidney Transplant Data Registries in the United States. JASN 2023. DOI: 10.1681/ASN.000000000000194)

6. CMMI seeks comment on its proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates.

Again, ASN appreciates CMMI's emphasis on successful achievement of a transplant itself as a major focus in this proposed model and agrees this ultimate outcome is an appropriate goal upon which to place significant focus. As a matter of principle, ASN also appreciates the simplicity of the approach. ASN offers suggestions for improvement to this promising foundation. The common theme across these suggestions is tempering expectations for growth and setting goals that are achievable. In a relatively inelastic system such as the nation's kidney transplant system, the goal of increasing kidney transplant rates is best pursued by setting attainable targets and rewarding progress with upside payments that can support investments in system change.

- **Set attainable achievement thresholds** ASN recommends that CMMI set realistic targets for the achievement thresholds. While ASN appreciates CMMI's desire to drive significant growth in terms of access to transplant, growth on the magnitude proposed (a multiplier up to 150% or more above past peak performance projected forward by the national growth rate year over year) does not appear to be feasible—nor consistent with CMMI's goal that the goals be attainable for IOTA participants. Growth at this rate would be a significant outlier throughout the healthcare system and practically impossible to sustain over any period of time.

As proposed, ASN believes most IOTA participants would conclude the goals are unrealistic or downright impossible and therefore not worth pursuing at all, leading to

broad disengagement. ASN **does** believe that under IOTA, many participating programs can perform higher than the national growth rate—but not at the proportions proposed.

ASN proposes the highest rate of achievement to be 25% or more than the national growth rate ($\geq 1.25 \times$ national growth rate).

For example, if a program has 100 transplants and the national growth rate is 10%, then it would be predicted to have 110 transplants the following year. ASN proposes a $\geq 25\%$ increase of the national growth rate (e.g. 25% higher than the 10%, which = 12.5%). The increase from 100 transplants in the prior year by 12.5% = 112.5 patients. ASN proposes this growth should be the highest tier of achievement.

ASN is **not proposing** a 25% increase in the transplant rate on top of the national growth rate (e.g. if a program has 100 patients and the national growth rate is 10%, a 25% increase of the **total** program would be $([100 \times 1.1] \times 1.25) = 137.5$, which would be more than 27 additional transplants that year.

- CMMI should apply the multiplier (≥ 1.25) ONLY to the national growth rate.
- CMMI should NOT apply the multiplier to the total number of people predicted to be transplanted at a program by the national growth rate.

Proposal	Approach
ASN	Applying the multiplier the national growth rate
CMMI	Applying the multiplier to the national growth rate and the growth rate to a total amount

Applying the multiplier to the national growth rate as ASN recommends is more likely to be within the range of achievability given the historical median annual growth of deceased donor transplants of 8.2%. (ASN also examined overall historical growth rate trends, which show a median national growth rate between 6% and 8% [Appendix 1 Table E].) We should note that given that the national growth rate each year will include IOTA participants, the IOTA model will result in more aggressive growth rate goals in each subsequent year.

In **Appendix 1** ASN has modeled transplant growth rate scenarios at the as-proposed 150% growth achievement rate based on past peak performance projected forward by the national growth rate, and numerous lower percent growth achievement rates projected forward by the national growth rate, to illustrate the unlikelihood of CMMI's proposal. Appendix 1 Table A and Appendix 1 Table B model CMMI's proposed growth on programs' past peak performance assuming a national growth rate of 10% (Appendix 1 Table A) and 5% (Appendix 1 Table B) for simplicity. Appendix 1 Table A and Appendix 1 Table B suggest that CMMI's growth targets, as proposed, are not likely to be even nearing achievability.

Under CMMI's proposal even assuming just a 5% national growth rate, a baseline 100-transplant program that achieved 150% growth (e.g. the top tier) annually would by year six be transplanting more than 1,500 patients per year. In the six years this single center alone would perform a total of 3,193 transplants (Appendix 1 Table B, line 18)—more than CMMI forecasts *all* 90 IOTA participants would generate combined attributable to IOTA during the six-year period (2,625 transplants [proposed rule Table III]).

ASN observes there appears to be a disconnect between the growth CMMI asks centers to attain for maximum points in the Achievement domain (up to 150% based on past peak performance projected forward by the national growth rate year over year [proposed rule table 3]) and the total of just 2,625 additional attributable transplants to IOTA total over the course of the six-year model (proposed rule Table III). To attain 2,625 total additional transplants, the ~90 IOTA participants would only have to perform a collective average of an additional ~5 transplants annually, which would translate into a very small net differential growth rate between IOTA and non-IOTA participants.

Instead, ASN recommends that CMMI apply the proposed multiplier bands outlined in proposed rule Table 3 (up to $\geq 125\%$) to the *national growth rate* instead of to programs' own past peak performance. Table C and Table D model ASN's proposed approach to incentivizing growth on the *national growth rate*, assuming a national growth rate of 10% (Appendix 1 Table C) and 5% Appendix 1 (Table D).

This approach would still yield **very** substantial growth in transplants over the course of the model. It would also be attainable for many centers, as well as perceived as sustainable. With current workforce challenges and typical space constraints, ASN believes incentivizing $\geq 125\%$ growth *on the national growth rate* is doable for some programs. It would create a clear differential between IOTA and non-IOTA programs for evaluation purposes and would allow for a much higher number of attributable kidney transplants than are currently projected, in part by ensuring greater engagement from participating centers. Many IOTA participants may not achieve a 50 percent higher growth than the national growth rate, but that growth will still be quite meaningful over the six years and in the aggregate across all IOTA participants.

For example, under ASN's proposal, assuming just a modest 5% national growth rate with 90 IOTA participants (all baseline 100 transplants) and assuming every participant achieves just a very modest 110% growth on that 5% national growth rate, approximately 50 additional attributable transplants would result at this one single hypothetical IOTA participant. (Appendix 1 Table D, line 50) which would result in the overall growth far exceeding CMMI projections of the effect of the model. (Appendix 1 Table D, line 50).

As noted, ASN does not believe that $\geq 125\%$ growth based on past peak performance projected forward by the national growth rate year over year is realistic, but ASN does believe that IOTA could generate **substantially** more than the proposed 2,625 additional transplants over the course of the six-year model. To do so, ASN proposes to encourage centers to achieve the maximum Achievement points by applying the $\geq 125\%$ multiplier to the *national growth rate*.

To reiterate, even expansion at the growth levels outlined in Appendix 1 Table D would be a significant challenge put possibly doable for a small percentage of programs that can attain top-tier performance in this scenario, which ASN thinks is aligned with CMMI's vision.

ASN recognizes that in recent years a couple of kidney transplant programs have demonstrated remarkable growth, nearing annual gains of the $\geq 125\%$ based on past performance. However, as demonstrated in Appendix 1 Table A and B, percentage growth gains of this size are not likely to be sustainable beyond a few years. And,

critically, these gains have been made possible by use of organs offered out of sequence and therefore cannot be replicated on a nationwide basis.

Appendix 1 Table F depicts the financial implications for a 100-transplant program under CMMI's proposed approach, a financial scenario ASN does not think CMMI intended to propose.

- **Set baseline performance as the highest volume of both living and deceased donation kidney transplants combined in a single year across the last three years** Living donor and deceased donor program resources are often shared in the form of pretransplant coordinators, navigators and other resources such as clinic capacity, and number of clinicians. Therefore, ASN suggests that CMMI select the year with the highest total volume of living and deceased donation kidney transplants combined among the three prior years as the historical benchmark. Particularly if the historical benchmark is proposed to be multiplied by a national growth rate, as proposed, it is important to set the base within reach in order to allow programs a chance of success.

ASN recognizes that CMMI also aims to create a clear focus on living donation, which this approach may detract from. CMMI could consider identifying the baseline year with the highest number of combined transplant types and then measure/reward subsequent growth in each domain, deceased and living. ASN realizes, however, that this approach would be more complex and would move away from the simplicity originally proposed, which is a strength of the model.

- **Set baseline performance using years most likely to be reflective of current state** CMMI proposes using 2021, 2022, and 2023 as the baseline three years upon which to base IOTA participants' historic transplant performance. ASN understands the desire to examine past performance across multiple years but suggests that CMMI look exclusively at 2022 and 2023. 2021 was an anomalous year in many ways and may not be reflective of normal practice (or current or future practice) for many transplant centers. For much of 2021, COVID-19 was still a significant force: some transplant centers did significantly lower volume as a result, and some others that continued doing transplants did so at a higher rate than they otherwise would have—in part because they received more high-quality kidneys that were available because other centers were doing fewer transplants. Additionally, 2021 was the first year KAS250 took effect, and centers were still adjusting to how to cope with the significant uptick in organ offers. While this recommendation is lower-priority than the others in this section, ASN believes 2022 and 2023 are superior years on which to base historic transplant rate performance.
- **Stratify growth expectations by kidney transplant volume** CMMI proposes to set the target number of kidney transplants for each program based on their historical performance during the baseline years multiplied by the national growth rate. ASN observes that the dynamics of increasing kidney transplant volume are likely to be different across different sizes of programs. In particular, ASN wishes to avoid an unintended dynamic in which certain centers find themselves struggling to achieve IOTA's goals and resign themselves to being poor performers, paying the relatively low downside risk payments.

Given the diversity of program sizes, and the relative advantages and disadvantages to rapid growth that accompanies each size, ASN recommends that CMMI pursue a

stratified national growth rate that compares growth at programs to the national growth at programs of a similar size. Such an approach would allow for the creation of realistic goals for programs and facilitate randomization at the outset of the model without the need for reclassification of centers between groups over time.

Appendix 2, which breaks out program growth rates by program size (11-50, 51-200, and >200) for 2021-2022 and 2022-2023 demonstrates that programs of different sizes grow at substantially different rates.

Accordingly, ASN suggests CMMI consider three national growth rates: one growth rate for the highest volume centers (>200 transplants per year), one growth rate for medium (51-200 transplants per year) and lowest volume centers (11-50 transplants per year), among centers that meet IOTA participation criteria.

- **Assign 50 instead of 60 points to the Achievement domain** ASN appreciates CMMI's focus on the outcome of kidney transplants as a major focus of the proposed model, versus on processes along the way. However, ASN suggests that greater emphasis is needed to encourage focus on, and investment in, supporting patients' longer-term (post one-year and longer) outcomes post-transplant. ASN wants increased access to transplantation and wants to encourage long-term success of those transplants. ASN recognizes and agrees with CMMI that as more marginal kidneys are used and as higher-risk patients are transplanted, the current 95%+ success rates seen in the first-year post-transplant may decrease—a predictable tradeoff for greater access that kidney patients have understandably asked for and that ASN supports, recognizing the MPSC will still be providing a backstop on quality and safety.

However, the society is concerned that with 60 points on Achievement and just 20 points on Quality (only 10 of which examine long-term outcomes), in the context of resource-scarce kidney transplant programs, resources will be pulled from efforts to help patients succeed in the long-term (post one-year) period in order to deliver success on increasing transplant rates. ASN understands that CMMI agrees that both of these goals are important and appreciates that CMMI has proposed a rolling composite graft survival metric (which is discussed in more detail later) to encourage a focus on longer-term outcomes. The society recommends that CMMI more closely align the points assigned to each domain in the performance score: 50 for the Achievement domain and 30 for the Quality domain, with 20 of those 30 points applied to the graft survival rate (keeping 10 points for other metric[s] in that domain).

Looking at the patient journey, kidney transplant centers already have more of a financial incentive to increase rates of kidney transplantation than to dedicate scarce resources to long-term outcomes. Organ acquisition costs related to pre-transplant care get reimbursed by commercial insurers for their patients and through the Medicare cost report by Medicare (for Medicare and MA patients); care during the 90-day perioperative period is reimbursed through the surgical DRG; and 90-day and one-year outcomes are the focus of OPTN and SRTR metrics. The care of increasingly complex patients or patients who received more complex organs has become more resource-intensive, with more readmissions and more labor-intensive care and a greater need for longer post-transplant dialysis for delayed graft function.

However, reimbursement for non-surgical post-transplant care provided by the kidney transplant program is largely provided by the same transplant nephrologist that provides

care pre-transplant. Recognition of care provided in the post-transplant phase by a transplant nephrologist is limited to transplant nephrologist's E/M codes (which are not tied to a sub-specialty transplant-specific RVU value) and there is less emphasis on outcomes post-one year in public reporting and oversight. A vast amount of non-patient-facing time spent by transplant nephrologists in providing post-transplant care (e.g. ordering/reviewing lab tests and other studies, coordinating care with general nephrologists, managing complications that don't require a patient visit, communication with patients/family members and other physicians, morbidity and mortality conferences, clinical case conferences) is not directly reimbursed.

Moreover, there is no reimbursement mechanism to cover the efforts of the large multidisciplinary care team (social workers, transplant pharmacists, nurse coordinators, medical assistants, financial coordinators, administrative staff) that supports the delivery of post-transplant care by transplant nephrologists. Since referring nephrologists invariably do not have these resources within their practices, the cost of supporting longitudinal post-transplant care largely falls on transplant hospitals and transplant nephrologists continue to provide care that is not directly reimbursed indefinitely to a growing and more complicated patient population. (Axelrod DA The Changing Financial Landscape of Renal Transplant Practice: A National Cohort Analysis. Am J Transplant 2017 Feb;17(2):377-389)

ASN also notes that much of the investment required to achieve success in IOTA are workforce, care coordination efforts, and transplant-readiness efforts—in other words, investment on the pre-transplant side of the process, outlays that can be potentially added to the cost report and thus at least partially reimbursed by Medicare. This reality underscores that since greater resources are accessible to support transplant center efforts during the pre-and peri-operative period, for reasons outlined in the preceding paragraph, CMMI may need to place more weight on performance on long-term outcomes than originally proposed in order to achieve its vision to “promote improvement in outcomes for the benefit of attributed patients...[and] build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible.” CMMI should also strongly consider that there is risk that the capacity of transplant programs to provide optimal post-transplant care could be overwhelmed if IOTA achieves its intended goals, leading to an unsatisfied patient population and disgruntled transplant workforce, potentially jeopardizing outcomes. Weighting the Quality Domain's graft survival rate more heavily may increase transplant centers' interest in investing in post-transplant care, including in an adequate workforce to meet these needs.

To summarize, there are substantially fewer dollars available to support post-transplant care in the current system than there are in the pre-and peri-operative period, and CMMI also proposes to place lesser emphasis in IOTA on outcomes after the first post-transplant year. Yet, as CMMI rightly outlines, this post-transplant care is critical to maintain the health of the graft and the recipient in the long term. As discussed above, the cost of the multidisciplinary care team that supports longer term patient outcomes primarily falls on the transplant hospital.

The reality is that in many areas, post-transplant care and the model's success will be dependent on IOTA participants engaging general nephrologists as key IOTA collaborators, as CMMI has proposed. The resources of IOTA as proposed are not sufficiently robust to significantly increase the transplant center workforce. Moreover, in many regions of the country, even if centers had more money, they would likely struggle to hire more staff to do post-

transplant care in light of current workforce shortages and would instead seek partnership with community nephrologists. ASN offers three potential pathways to alleviate these challenges for CMMI's consideration:

- Create, within the model, a Monthly Capitated Payment (MCP) for post-transplant care. With a secure, regular revenue stream for post-transplant care as there is in dialysis care, community nephrologists will engage more readily in the care of these patients.
- Establish an RVU adjustment for the care of transplant patients in the model regardless of the nephrologist type, (e.g. transplant or general nephrologist).
- Increase resources to support more robust longer-term post-transplant care coordination with general nephrology partners for patients that are referred back to the transplant center. Increasing the size of upside payments that could be shared with collaborators is one approach, though dedicated funds to IOTA participants would be preferable.

Lastly, ASN suggests that CMMI consider adding a bonus for pre-emptive transplantation or adding a pre-emptive multiplier altogether. The society recognizes that pre-emptive transplantation is not a socioeconomic category like the other proposed 1.2x eligibility criteria but appreciates that CMMI also considered offering differential credit for pre-emptive transplants. Pre-emptive kidney transplants offer major survival and quality of life benefits for patients, as well as major cost savings. Recent studies indicate savings from pre-emptive kidney transplants begin to accrue as soon as 6-7 months post-transplant as compared to maintenance dialysis, with net one-year savings of more than \$100,000 and three-year savings of nearly \$300,000 (Healthcare Costs Among Pre-Emptive Kidney Transplant vs. Maintenance Dialysis Patients: A Real-World Study. Schold JD et al. Poster presentation, American Transplant Congress. June 1-5, 2024; Preemptive Kidney Transplants Lead to Cost Savings in Less Than a Year. Dawahn R et al. Poster presentation, ASN Kidney Week 2022. JASN 33(11S) p. 835, November 2022.)

As noted on page 50 of the proposed rule, fewer than 3 percent of patients in the U.S. received a pre-emptive transplant, a significantly lower rate than other similarly developed countries, suggesting ample room for improvement. (United States Renal Data System. 2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7.) Given the substantial benefits to patients and the substantial savings as compared to dialysis, ASN suggests CMMI consider creating a pre-emptive bonus or pre-emptive multiplier, which could be scaled commensurate with savings to the Medicare program pre-emptive transplants confer relative to maintenance dialysis. ASN also emphasizes that the calibration of such a bonus or multiplier would need to be done carefully, ideally with input from the community, and closely monitored to ensure the multiplier succeeds in having the intended effect of expanding the populations receiving a pre-emptive transplant instead of deepening the inequities in access to pre-emptive transplant.

7. CMMI seeks comment on the proposed health equity performance adjustment, the definition of low-income population and alternatives considered, and consideration of ADI as an alternative definition, and including rural resident in the low-income population definition.

Ample literature documents that the patient populations for whom CMMI proposes eligibility for the health equity performance adjustment (a 1.2x multiplier to an IOTA participant's transplant rate), such as those who are Medicaid beneficiaries or who are otherwise socioeconomically disadvantaged—for example, people who qualify for the Medicare Low-Income Subsidy [LIS], have historically had worse access to transplant care compared to more affluent beneficiaries with kidney failure, even when they are medically suitable candidates. For example, in a recent

study, just 49% 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 gaps in access to optimal care for reasons other than health status. (Husain S et al. Disparities in Kidney Transplant Waitlisting Among Young Patients Without Medical Comorbidities JAMA Intern Med. doi:10.1001/jamainternmed.2023.5013; Wadhvani S et al. Medical Need, Financial Resources, and Transplant Accessibility. JAMA. 2022;327(15):1445-1446. doi:10.1001/jama.2022.5283; Dubai D et al. Insurance Type and Solid Organ Transplant Outcomes. J Am Coll Surg. 2016 Oct; 223(4): 611–620.e4.; Schold JD et al. Failure to Advance Access to Kidney Transplantation over Two Decades in the United States. JASN April 2021. doi: 10.1681/ASN.2020060888; 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)

ASN strongly supports the concept of a multiplier that encourages focus on supporting patient populations who are medically good candidates but who face socioeconomic status (SES)-related barriers in successfully obtaining a kidney transplant as well as adequately supporting them in the post-transplant period. To achieve that goal, it is important that the multiplier be substantial enough to give centers sufficient resources to support these patients in overcoming SES-related barriers to transplant. For example, centers will likely need to hire additional patient navigators in the pretransplant period (pre-transplant access coordinator) followed by additional financial coordinators and social workers to support these patients through the pretransplant process and the post-transplant experience (post-transplant quality coordinator). Similarly, helping a patient with low health literacy navigate the system requires more transplant center time and effort than a patient with high health literacy.

At present, the transplant system has erected numerous barriers to accessing a kidney transplant that *are directly related to socioeconomic status*. These barriers have always been rooted in well-intentioned efforts to steward the scarce resource of kidneys. For example, some programs require a minimum balance in patients' bank accounts to be eligible for a transplant out of concern for medication costs, even for insured patients (concerns that may be outdated due to the Affordable Care Act, 340B programs, and the enactment of immunosuppressive drug coverage legislation).

In practice, helping many of the candidates who struggle to access kidney transplantation due to socioeconomic-related factors is theoretically feasible—particularly in the context of the waivers CMMI has proposed—however, doing so requires resources that are not sufficiently accounted for in the model (much less in the current kidney transplant reimbursement system). Besides tangible barriers such as access to transportation, there are also more resource-intensive intangible barriers that must be overcome to help certain patients who are medically good candidates access a kidney transplant.

ASN strongly supports the goals of helping socioeconomically disadvantaged patients overcome barriers and access a kidney transplant but believes that CMMI must provide the requisite resources to enable transplant centers to achieve this worthy goal.

ASN also requests that CMMI share more information regarding the percent of the patient population eligible for the multiplier, by eligibility category. ASN is particularly interested in any regional differences in eligibility by category, and what kind of overlap exists between eligibility categories. The society recognizes that some states have expanded criteria for Medicaid but believes that differences in the percent of patients that qualify for the multiplier between states

that have and have not expanded Medicaid may be attenuated or erased based upon eligibility for the multiplier due to LIS status or NLDAC eligibility. ASN requests that CMMI share this data in the final rule.

Additionally, responding to CMMI's consideration of Area Deprivation Index (ADI) as a possible alternative, ASN concurs it is a less optimal path than what CMMI ultimately proposed. ADI is a more difficult criterion for a transplant center to identify who would qualify (and intervene) – so in the interest of simplicity, one of this model's greatest strengths, ADI would be less effective at driving behavioral change at the center level than the clearly-identifiable SES eligibility criteria CMMI has proposed. While the ADI is a good tool, centers usually have a much more granular evaluation of individual-level SES and can thus designate which patients should be identified for additional support easily and immediately.

Lastly, as discussed in more detail in the Quality Domain section, ASN also recommends that CMMI apply a parallel multiplier to the post-transplant graft survival metric.

In sum, ASN appreciates CMMI's intent of helping individuals who face barriers to the best, most cost-effective treatment, but urges CMMI and CMS to resource transplant centers appropriately to help the patients overcome the barriers they face.

8. CMMI seeks comment on its proposal to use and calculate the OPTN organ offer acceptance rate ratio for assessing Efficiency Domain performance, and alternatives considered.

ASN generally supports CMMI's proposal to use the OPTN organ offer acceptance rate ratio to comprise the entirety of the basis for the Efficiency Domain score, for the reasons CMMI outlines in the proposed rule. ASN believes this metric is generally well-understood by the community and is a widely agreed-upon approach to create accountability and improve efficiency. As outlined, IOTA participants have control over this existing metric, which serves to recommend it above possible alternatives where control over success is diluted across multiple stakeholders. Programs can improve their performance by either accepting more organs that are offered or narrowing their organ offer filters to avoid offers they are unlikely to accept—creating greater efficiency in the system and ideally allowing more organs to be placed and used in a timely fashion.

At present, there is a wildly disproportionate relationship between the number of offers that are made to the number of kidneys accepted for transplant, contributing to inefficiencies in the system and higher non-use rates. This organ offer acceptance rate ratio metric should make some progress towards rightsizing the number of offers participants receive relative to their number of acceptances by promoting the responsible use of organ offer filters and encouraging “yeses,” where appropriate. ASN notes that this metric could also motivate centers to decrease the use of “internal holds,” a relatively non-transparent process that may be overused, and actually remove patients from the waitlist who are not good candidates—minimizing unnecessary time and resources spent on waitlist management and setting more realistic expectations for patients.

ASN also encourages CMMI to consider how best to deal with allocations out-of-sequence (OOS) in the context of IOTA in general and within this metric in particular. The number of kidneys placed OOS has grown exponentially in recent years and even recent months: As of December 2023, more than 20% of kidneys were placed OOS [OPTN MPSC data, OPTN Board of Directors meeting, Monday, June 18, 2024] To the extent that OOS result in successful

transplants of kidneys that would have otherwise gone unused, allocations OOS may provide a net benefit, however, substantial data suggests that many of the kidneys placed OOS do not meet traditional criteria for being hard-to-place organs. (King K et al Deceased donor kidneys allocated out of sequence by organ procurement organizations. *Am J Transplant.* 2022; 22:1372–1381). No clear oversight of which patients receive these organs (and do so at the expense of patients who are listed at transplant centers with higher sequence numbers that were overlooked in an effort to place these organs) exists. Given that out of sequence placements are being used for organs across the quality spectrum and with no clear evidence that this practice is effectively lowering discard rates, their inclusion in measures of success for IOTA risks inadvertently exacerbating disparities.

In one 2021 study, at the two transplant centers that used OOS placements the most often, recipients who received transplants using OOS kidneys tended to be older, white, have private insurance, and get the transplant preemptively as compared to the centers' transplanted patients who received kidneys in-sequence via the match run. (King K et al Deceased donor kidneys allocated out of sequence by organ procurement organizations. *Am J Transplant.* 2022; 22:1372–1381).

The match run algorithm exists to create as objective and fair access as possible to available kidneys. Allocations OOS rely on relationships between a given organ procurement organization and transplant center, introducing more subjectivity and the possibility of lesser access to kidneys for patients who are at transplant centers that lack those relationships. This reality is worth considering in a model that focuses on equity in access to kidney transplantation for all candidates, and allocations OOS have the potential to affect outcomes in IOTA: CMMI will need to monitor patterns and examine effects of allocations OOS on model results closely.

ASN suggests that CMMI consider the pros and cons of excluding transplants conducted using kidneys placed OOS from IOTA participants' performance scores, observing that if CMMI does not exclude them, it may de facto encourage greater adoption of allocation OOS practices among IOTA participants. Such adoption would adversely impact access to transplant at other centers, undermining the health equity goals of the model. Organ offer acceptance rates are particularly prone to disproportionate inflation with the addition of out-of-sequence kidneys.

The OPTN recently approved a variance that would allow limited testing of OOS via pre-specified, time-limited (3-month) protocols for a limited number (approximately 5-10) of OPOs and their prespecified (not geographically limited) transplant centers at a time. If deemed successful, those protocols could be incorporated as permanent policy into an updated allocation algorithm. Depending on how it is implemented, this change could potentially result in a 2-tier transplant system with greater access to the deceased donor organ pool for some centers compared to others, while also potentially permitting some centers to allocate organs to patients of their choosing rather than adhering to the allocation sequence. ASN suggests that CMMI also closely monitor the effect of participation in protocols under this variance on IOTA participants (and non-participants') performance, especially to the degree that more and more protocols are simultaneously piloted nationwide (potentially influencing a greater number of IOTA participants and non-participants performance). ASN would be pleased to provide more detail to CMMI's evaluation team along these lines, if helpful.

9. CMMI seeks comment on its proposal to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN’s measure specifications and SRTR’s methodology as the metrics that would determine IOTA participants’ performance on the efficiency domain, as well as the ratio performance scoring methodology, including on the achievement and improvement score calculation and point allocation method.

ASN supports the use of the measure specifications and SRTR’s methodology with the caveat that centers that have a disproportionately high use of out of sequence kidneys have inflated organ offer acceptance ratios.

ASN supports the use of both an achievement and an improvement score and supports selecting the highest of the two to evaluate IOTA participants. Similar to ASN’s comments on point allocation for other domains, the society urges CMMI to moderate the proposed expectations for performance in the Efficiency domain to earn points (and upside payments that can help IOTA participants succeed in the model) for both achievement and improvement scores.

Lastly, inspired by CMMI’s 1.2x multiplier proposal and ASN and CMMI’s shared interest in encouraging the use of kidneys that are at risk of non-use but that may benefit patients interested in accepting kidneys of this quality, ASN suggests CMMI consider a multiplier for “hard to place” kidneys, using the SRTR definition of “hard to place” kidneys as those that were placed above sequence number 100. Hard-to-place kidneys are likely to accrue more cold ischemia time and therefore more likely to experience DGF regardless of organ quality. Given the increased costs associated with DGF, providing an incentive to use these organs would be valuable. Such a multiplier could be applied to either the Efficiency Domain (where it would be consistent with the focus on increased offer acceptance) or the Achievement Domain (where it would be consistent with the focus on greater transplant rates). CMMI may wish to consider a phased-in multiplier to avoid gaming near the sequence number 100 mark.

10. CMMI seeks comment on its proposed quality measure set that includes two PRO-PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain.

ASN appreciates CMMI’s focus on including patient-reported outcomes metrics in IOTA and concurs that encouraging greater patient input in the kidney transplant process than at present is a crucial goal. However, because the CollaboRATE measure and the 3-Item Care Transition measure have not been validated in this patient population yet and would require a not insubstantial effort to administer and document, the society is concerned they will increase the burden on both transplant centers and patients without meaningfully improving care. As described later in this letter, ASN strongly supports the development of a HRQOL PROM and suggests CMMI invest in developing a measure(s) along these lines for incorporation into IOTA as soon as possible.

The society also recognizes that CMMI is invested in having the same quality measures in as many models as possible, which inclusion of the Colorectal Cancer Screening measure may help advance. However, ASN suggests that CMMI could instead use a measure for screening for post-transplant diabetes mellitus or management of hyperlipemia. ASN believes addressing post-transplant cardiovascular risk factors would have more benefit in long term outcomes

wherein multiple adverse cardiac events are more frequent causes of death than cancer or infection.

ASN also considered suggesting that CMMI consider using a vaccination rate measure in place of the Colorectal Cancer Screening measure. Being current on vaccinations is more directly relevant to transplant candidate readiness and transplant recipient well-being regardless of age than colorectal cancer screening (which is only age-applicable to a subset of the IOTA beneficiary population). However, the society acknowledges that vaccination rates may present an evolving challenge for transplant centers to achieve given the growing skepticism of vaccinations in the post-COVID-19 pandemic era.

Many programs exclude individuals who refuse vaccinations who would otherwise be good candidates, and such a metric may further encourage the exclusion of these patients. Programs that don't exclude people who remain unvaccinated would potentially begin excluding them or run the risk of performing poorly on this metric because they are willing to transplant that group. Setting an appropriate threshold for vaccination rates could acknowledge the presence of vaccination hesitancy among small numbers of patients at most centers without precluding their eligibility for transplant or forcing centers to create new strict exclusion criteria.

ASN suggests the development of additional post-transplant measures that can be used as measures for the quality of care provided, surrogates for long term allograft function, as well as early indicators for allograft function that can be intervened upon. Measures of kidney function at 12 months or new onset albuminuria (e.g. urine albumin to creatinine ratio [ACR]) are potential examples that are worth considering.

11. CMMI seeks public comment on its proposal to evaluate IOTA participants on posttransplant outcomes using our new composite graft survival rate metric, as well as on the alternatives we considered.

As noted earlier, ASN appreciates CMMI's emphasis on encouraging focus on post-transplant outcomes beyond the one- (and three-) year time horizon that currently receive the most focus. ASN broadly supports the proposed rolling composite graft survival metric as a mechanism to do so, and in particular, appreciates the simplicity of the proposed approach. ASN offers some suggestions for improvement, below.

ASN and CMMI share the goals of both increasing access to kidney transplantation and improving long-term outcomes. In some ways, in the current regulatory environment, these goals are at odds with one another. Overall, the society wants to encourage greater organ utilization and greater access to transplantation—as well as to ensure post-transplant outcomes are still superior to dialysis and that patients' quality of life and well-being are better than when on dialysis. In order to balance the appropriate increased emphasis in IOTA on transplanting kidneys or patients that may not be under current regulatory dynamics as well as appropriately encourage increased emphasis on successful long-term outcomes, ASN recommends that CMMI integrate risk-adjustment for at least a few variables.

ASN recognizes that this approach is not *perfect* risk adjustment but does not want to let the perfect be the enemy of the good – or the simple and easily understood.

Specifically, ASN suggests that CMMI risk-adjust for at least a small number of variables that would allow for a simple model that is understandable by including the biggest drivers for variation in outcomes and thereby disincentivize the creation of additional hurdles for more

complex patients. For example, a model that includes age, ESRD vintage, and diabetes mellitus (y/n) would leverage currently available data and remain easily measurable and understood.

Additional significant variables that can be captured objectively and would meaningfully improve performance of the risk adjustment should be considered (e.g., measures of SES with surrogates like insurance type, organ type or quality) while remaining consistent with the efforts across IOTA to ensure that the measures are easy to understand and respond to.

ASN readily acknowledges that the above list of recommendations does not approach a comprehensive list of the known drivers of graft failure. For example, history of aggressive FSGS or other forms of glomerulonephritis, history of cardiovascular revascularization by coronary artery bypass graft or percutaneous transluminal coronary angioplasty (PTCA) stent prior to transplant, or history of malignancy prior to transplant, are reasonable comorbidities to consider for risk-adjustment. However, because these data are either not collected at all or are not collected in a reliable manner on these patient characteristics, comprehensive risk adjustment models are not at, present, feasible. In future years, OPTN data collection and repositories should be modernized to collect these and other pertinent data elements (though ASN notes the prerequisite step is the development of a standardized data dictionary for transplant nephrology). While outside the scope of IOTA, ASN encourages the Department of Health and Human Services (HHS) broadly to prioritize these foundational investments in data standards and IT as soon as possible through the OPTN Modernization Initiative, working in close partnership with the kidney and transplant community on the development of these data standards and elements.

ASN appreciates that CMMI considered using eGFR at 12 months as a measure of quality and thinks this concept merits additional consideration. On a population level, data suggest that eGFR at 12 months is predictive of long-term outcomes. Again, reflecting the simultaneous goals of increasing organ utilization and patient access, as well as outcomes that are superior to dialysis, ASN recommends that an appropriate gauge of success in such a measure may be an eGFR superior to dialysis initiation or listing for re-transplant (e.g. greater than 20 mL/min) such as 25 or 30 mL/min.

In sum, ASN recommends CMMI use a simple risk adjustment model that is easily understood, providing IOTA participants some reassurance that key drivers of variation in successful outcomes have been accounted for—ideally, creating more latitude to transplant patients or kidneys that may once have been passed up.

In addition to the minimal risk adjustment recommended above, ASN also recommends that CMMI apply the same 1.2x multiplier to the Quality Domain as proposed for the Achievement Domain. Helping patients keep their graft healthy in the long-term is a critically important aspect of quality transplant care, and many of the same challenges that socioeconomically disadvantaged patients face in the pre-transplant period persist in the post-transplant period. ASN believes that applying at least the same 1.2x multiplier to the Quality Domain would encourage IOTA participants to invest more time and focus on supporting these individuals in the long run and would appropriately reflect the intensity of care required to keep them stable. Given that some pre-transplant costs incurred by programs in responding to the health equity measures within IOTA would be borne by the OACC, a multiplier for post-transplant care would ideally be larger.

ASN also encourages CMMI to include uninsured patients as eligible for the multiplier for the Quality Domain. This approach would help mitigate concerns about transplanting patients who may experience a loss of coverage post-transplant—particularly for socioeconomically disadvantaged patients under age 62, who lose Medicare eligibility on the basis of ESRD 36-months post-transplant, do not yet qualify for Medicare on the basis of age, and may struggle to obtain alternate coverage in a timely fashion. As IOTA (appropriately) places greater emphasis on long-term transplant outcomes, it becomes even more important to mitigate disincentives to transplant socioeconomically disadvantaged patients. While loss of coverage is likely a rare event, such a multiplier for uninsured patients post-transplant would help to make the system fairer for small, vulnerable populations by decreasing the need for screening behavior based on perceived future weaknesses on patients’ financials.

As previously noted, ASN recommends that the Quality Domain consist of 30 total points: 20 points allocated to the graft survival measure and 10 points to the other measure(s) included in the domain. This point shift would appropriately encourage centers to invest in supporting long-term graft survival and appropriately balance the focus on growing transplant rates initially.

The society also recommends that CMMI adjust the eligibility to obtain maximum points downward in the composite graft survival rate scoring component of the Quality domain from the 80th to the 60th percentile, consistent with ASN’s recommendation to make upside payments more achievable while still incentivizing significant improvement relative to current practices.

Table 1: Potential Alternative Composite Graft Survival Rate Scoring (20 Point Maximum)

Performance Relative to Target	Points Earned
60 th Percentile	20
50 th and <60 th Percentile	15
40 th < and < 50 th Percentile	10
20 th < and < 40 th Percentile	5
<10 th Percentile	0

12. CMMI seeks comment on the proposed two-sided risk payment design to incentivize model performance goals.

ASN understands the complexity inherent in value-based care (VBC) and the need to provide two-sided risk to properly calibrate a payment model. The society’s larger concern rests with whether ASN believes IOTA is properly balanced in upside and downside risks. The society’s larger concern rests with whether ASN believes IOTA is properly balanced in upside and downside risks. As detailed below, ASN does not believe either the upside or downside are robust enough to be able to create interest for hospital leadership that eventually determines whether to provide transplant programs with the resources necessary to accomplish the goals of the model. These concerns are compounded by the fact that kidney transplantation is seen as a low-margin procedure for many centers with some centers operating near or at a loss. As discussed elsewhere, ASN is also unconvinced that the complete potential savings of the model have been captured.

13. CMMI seeks comment on the proposed methodology to calculate the upside risk payment and alternatives considered. CMS also seeks comment on the proposed methodology to calculate the downside risk payment and alternatives considered.

CMS has proposed the “upside risk adjustment” to be a fixed, risk-based payment amount of \$8,000 and a “downside risk adjustment” of \$2,000. ASN firmly believes that both the upside and downside risk calculations are insufficient to accomplish the goals of IOTA—either to fund the investments that will be essential for transplant centers to make to succeed in the model or to capture the attention of hospital and health system administrators in a manner that prompt them to do anything other than pay a downside “fine” which would mean that they essentially will not make any of the changes that were being incentivized by the model.

As CMMI is aware, kidney transplant has the lowest Diagnosis Related Groups (DRG) payments associated with any solid organ transplant and some kidney transplant programs operate in the red—in contrast to other solid organ transplant programs. Thus, at the end of the day, CMMI needs to make the incentives in IOTA substantial enough that not investing in the expansion of the kidney transplant program becomes an untenable opportunity cost. ASN strongly supports the goals of IOTA and recommends the following revisions to the upside and downside payments in the spirit of structuring IOTA, and enabling its participants, to be successful in achieving those goals.

To inform ASN’s recommendation, the society began with an examination of national utilization of kidney transplant Diagnostic Related Groups (DRG) 650, 651, and 652 at Medicare inpatient hospitals as reported [for 2022 by CMS](#) and in the May 2024 Milliman report (https://www.milliman.com/-/media/milliman/pdfs/2024-articles/5-14-24_milliman-kidney-transplant-lds-report.ashx).

Today, including all US transplant centers, approximately 35% of kidney transplants are DRG 650 or DRG 651, of which 75% are DRG 650 and 25% are DRG 651. ASN has been comparing profiles at small, medium, and large centers to confirm that this distribution of kidney transplants is sufficiently common for this discussion. As stated above, ASN is working on the premise that an increase in transplants coding DRG 650 and 651 will occur under IOTA.

Table 2. Distribution of Kidney Transplant DRGs by National Utilization and Reimbursement Rates (2022)

DRG and Description	% of Kidney Transplants Billed Under DRG	Base DRG Rate
650: Kidney transplant with hemodialysis with major complication or comorbidity	25%	\$51,400
651: Kidney transplant with hemodialysis without major complication or comorbidity	10%	\$42,300
652: Kidney transplant	65%	\$34,000

As shown in **Table 2** in the column “Base DRG rate”, the reimbursement difference between DRG 652 and DRG 651 is approximately \$8,000 (notably similar to the proposed maximum upside risk). The reimbursement difference between DRG 652 and DRG 650 is approximately \$17,000. The reimbursement difference between DRG 651 and DRG 650 is approximately \$9,000.

ASN believes it is appropriate to assume that under the IOTA model, the proportion of kidney transplants that are more complex is expected to increase (as more marginal deceased donor organs are used) as is the proportion of patients who are medically complex (reflecting IOTA-motivated transplantation of more patients who would benefit from kidney transplantation but who would otherwise not have been transplanted). Thus, the society would logically anticipate that the proportion of patients developing major complications and/or requiring inpatient dialysis post-transplant due to delayed graft function (DGF) is also expected to increase under IOTA leading to the increasing proportion of DRG 650 and/or 651 kidney transplants, rather than DRG 652.

Below are some potential scenarios for DRG growth and implications for incentives.

Unweighted DRG distribution: Assuming that the growth in DRG usage is split evenly (50% and 50%) between DGR 650 and 651, the mean average allowed cost/case would be:

$$(\$51,400 + \$42,300)/2 = \$46,750$$

The delta between this mean average allowed cost and DRG 652 = $\$46,750 - \$34,000 = \$12,750$

\$12,750 would be the recommended incentive per case in this scenario

Weighted DRG distribution: However, ASN believes it is more likely that the growth in DRG usage will be split unevenly under IOTA (75% and 25%) between DGR 650 and 651, as more complex kidneys and patients are transplanted. In this scenario, the mean average allowed cost/case would be:

$$([\$51,400 \times 3] + \$42,300)/4 = \$49,125$$

The delta between this weighted mean average allowed cost and DRG 652 = $\$49,125 - \$34,000 = \$15,125$

Therefore, ASN recommends **\$15,125** for upscale risk.

ASN should also note that published estimates of increased costs for patients that experience delayed graft function were approximately \$12,000 on average for the initial hospitalization across the country – with higher volume centers experiencing smaller increases in cost. (Kim D et al. Financial impact of delayed graft function in kidney transplantation. Clin Transplant. 2020 Oct;34(10):e14022) Encouraging transplant centers to take on more complex patients and organs will require incentives that cover these increased costs.

In terms of downside risk, the society recommends a proportional amount of downside risk relative to the original proposal (4:1):

Table 3. Alternate Proposal for Upside and Downside Risk risk

	Upside	Downside
Proposed by CMMI	\$8,000	\$2,000
Recommended by ASN	\$15,125	\$3,750

While ASN makes these calculations with a goal of transplant centers making investments that will translate into greater elasticity within the transplant center enabling the center to utilize a greater number of deceased donor kidneys being offered, the society realizes that there is likely to be an incremental process used by many hospitals – particularly in the first year. Many hospital administrators will do opportunity cost calculations and put any resources from IOTA wherever it will be the most profitable for the transplant center overall, not necessarily in staffing for kidney transplantation.

As one nephrologist in hospital management characterized it, “IOTA Year 1: we will be asked to do more with what we have in the kidney transplant program. If we are successful, in Year 2, we will see what growth looked like in Year 1, and then we might get more resources (or not) depending on the opportunity cost.” Importantly, some percentage of bonuses from IOTA may go to aspects of the transplant center that are not related to kidney transplant.

In particular, hospital and health system management will be weighing how to allocate the following resources across all solid organ transplant programs:

- Clinic space and schedules
- Operating room space and schedules
- Anesthesia staff
- Multidisciplinary staff including social worker, psychologist, dietician, pharmacist
- Laboratory and pathology services
- Specialty clinics for pre transplant cardiac and malignancy screening testing
- Transplant professional workforce shortages

Transplant professional workforce shortages, which are ubiquitous now, will be even more of an issue in the later years of IOTA, as kidney transplant programs start to show growth.

Again, the IOTA incentives need to be large enough to attract the hospital/health system administration’s attention, and the downside needs to be sufficient to make centers want to avoid having to pay it altogether.

In **Appendix 3**, ASN lays out several scenarios (Scenarios A-E) regarding how transplant programs may fare at varying levels of upside and downside risk. These calculations reflect:

- Hiring 2 RN clinical coordinators: These coordinators would focus on the core aspects of IOTA – increased patient outreach and engagement, increased living donor program, engagement of patients on the waitlist and discussion related to organ offer choices and filter selection.
- Hiring 0.1 FTE transplant nephrologist effort for the administrative aspects of the transplant program that need to grow for success in IOTA. (However, ASN notes that in practice, this will likely end up being additional unreimbursed work for the medical director)

- Hiring a patient care navigator (social worker) who is primarily outpatient with emphasis on social determinants of health (SDOH), education and patient navigation, particularly for those individuals who would meet eligibility criteria for CMMI's proposed 1.2x multiplier in IOTA

These calculations also include salary growth, meaningful fringe benefits to salaries, an option for OACC, and the option of potentially adding an additional transplant nephrologist in the later years of the model (PY5 and PY6) to help manage the growing population of post-transplant patients.

14. Regulatory Impact Analysis/1. Analytic Baseline

ASN wishes to draw attention to text in section V. Regulatory Impact Analysis/1. Analytic Baseline that not only potentially impacts the dollar amounts CMMI is willing or able to put into upside risk but also raises questions about the internal consistency of CMMI's expectations for the model results.

CMMI writes "For the proposed model, we assumed an average of \$40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis." The estimate of \$40,000 in savings over a 10-year period seems quite low to ASN and is inconsistent with other estimates. For example, the 2023 USRDS shows that FFS kidney transplant recipients were more than \$55,000 less costly annually than hemodialysis patients. (United States Renal Data System. Table 9.11. *2023 USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2023.) ASN requests that CMMI revisit this discussion and provide a more detailed regulatory impact analysis that shares the assumptions, data sources, and math that went into that estimate.

Additionally, in light of the previously noted findings that pre-emptive transplants yield nearly \$300,000 in savings at the 36-month mark, and break even with maintenance dialysis at roughly 6 months, ASN also requests that CMMI predict what savings in the model would be if CMMI were to finalize ASN's recommendation for a pre-emptive transplant multiplier that would drive an uptick in pre-emptive transplantation and related savings, even if that uptick is modest.

Sharing the assumptions and data sources and updating the projected per-transplant savings and projected net transplants/savings is important for transparency's sake. Together with ASN's recommendation to apply the proposed multiplier bands outlined in proposed rule Table 3 to the *national growth rate* instead of to programs' own past peak performance, such an update is likely to yield significantly more savings. Those savings could be shared with IOTA participants via upside risk payments more so than originally proposed as well as save Medicare funds.

Lastly, ASN observes that Table III appears to have an error: the projected \$100 million impact on FFS spending should be \$105 million (assuming \$40,000 per transplant x assuming 2,625 additional transplants = \$105,000,000), yielding a mean net savings of \$70 million to Medicare after projected net payments of \$35 million to IOTA participants. ASN thinks both transplant growth and per-transplant savings could well be larger, but notes the potential inaccuracy in this scenario nonetheless.

15. CMMI solicits public comment on whether an alternative frequency of sharing of organ offers with the Medicare beneficiary is more appropriate.

In general, ASN strongly supports greater transparency for patients and appreciates IOTA's focus on increasing their ability to have insights into decisions made on their behalf as well as greater understanding of how the system itself works.

ASN supports sharing information about organ offers with patient, both on the principle that people should have access to information about their care and with the goal of prompting greater patient input into the decisions made on their behalf. ASN offers some suggestions for improvement to the approach to sharing this information for consideration by CMMI and CMS as well as HHS and the Health Resources and Services Administration (HRSA).

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. (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) Between 2015 and 2022, the number of offers (excluding offers of discarded organs, e.g. only offers that went on to be transplanted) made annually to unique candidates on the kidney waitlist grew more than threefold, from 13.02 to 42.93 offers. During that time period (2015-2022) 20.1% of patients who had received at least one offer that was transplanted into another patient died waiting or were removed from the waitlist because they were too sick to transplant. (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).

Not every patient may 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 society recognizes it would be a major undertaking by transplant centers and would require additional resources to help educate patients, their families and referring physicians of offer declines. Decisions are often nuanced and intangible unless one has very clear insight. Automated information will only be acceptable to some patients, and many will be contacting their care team for a better explanation.

It is important to appropriately define the declined organ offers, the timing, and the context that should be shared with patients so that the information provided is meaningful and useable. The society suggests that:

- Offer declines should be shared less frequently than monthly: twice annually would constitute timely information-sharing without being so frequent as to be burdensome for either the recipients or the providers of the information.
- Offer declines should be shared only for organs that went on to be successfully transplanted in other patients, both keeping the volume of information manageable¹ and

¹ For example, one large midwestern program with a higher-than-average offer acceptance ratio declined nearly 9,000 offers for approximately 200 patients.

focusing on kidneys that were sufficiently high-quality for transplant: 90% of offers are generated by kidneys that ultimately are not used (discarded). (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) Eliminating these from the information sharing would significantly and appropriately limit the offers shared with patients.

- Offer decline codes include the reasons that a center reports as the reason for declining an offer and are currently available from the OPTN. They should be included in the information that is provided, offering context and the rationale behind the decline.
- 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 between the patient, referring nephrologist and transplant program.
- Offer declines should be shared only to a certain sequence number in the match run, keeping the information to a manageable amount and focusing on organs that the patient had a reasonable likelihood of receiving.

What is the “right” sequence number at which to cap organ offer decline sharing? At present, only a small fraction of organs are accepted for the individuals at the top of the match run: kidneys are offered on behalf of a median of 7 waitlisted patients before being accepted for transplant, with 25% of kidneys offered to at least 73 candidates before being accepted and successfully transplanted (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) Besides informing a range within the match run at which organ offers should be shared with patients, these statistics underscore why it is important to share this information with patients: quality kidneys are frequently passed over on behalf of patients who had a higher sequence in the match run, unbeknownst to the patients. Given that one-quarter of offers are accepted at or after having been offered to 73 patients, ASN suggests that organ offer declines should be shared with candidates up to match run sequence 150, double that. 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.

ASN recommends that existing technology and information that is already collected be leveraged as much as possible to minimize the burden on transplant centers. For example, organ offer decline information is already collected by the OPTN via decline codes. Rather than transplant centers investing additional resources in delineating the decisions, this information could be made available to patients and their nephrologists either through direct communication from the OPTN to patients or by the creation of a transplant center-specific report(s) that would lower the center’s administrative burden of sharing this information with patients.

CMMI proposes that transplant centers be responsible for sharing this information with patients via a manner of their choosing. ASN recommends that as soon as possible for IOTA participants—and as soon as possible thereafter for all transplant centers—the HRSA and the OPTN develop an automated mechanism to support transplant centers in sharing this information with patients and their referring nephrologist. All the relevant information already exists in the OPTN database and a twice-annual report could be generated and shared electronically, such as through the transplant center’s patient portal. 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 Transition and/or Next Gen contracts.

Automating as much of the data-sharing with patients is essential to keep transplant nephrologists and other transplant professionals' time available for these conversations, as needed. In the meantime, IOTA participants could leverage the Organ Offer Report or a future iteration of this report. The OPTN makes the Organ Offer Report available to every transplant program, including data on 180 days of organ offers to candidates at each transplant program, as well as information about organs that were ultimately declined and later transplanted at other centers.

Until the OPTN is capable of providing this information on an automated basis through Modernization Initiative-enabled capabilities, the time effort and cost of that time on behalf of IOTA participants should be added to the cost report, as well as the time and cost of discussing the information with patients as needed—and the latter should continue in perpetuity. Some patients will opt out of receiving this information, and some patients will desire more help in understanding the data and what it means for their care in the future. The nuances of organ selection and the potential outcomes associated with those decisions are complex conversations that are likely to be time consuming. Skilled personnel who understand the allocation system and can meaningfully translate this information for patients are also in short supply.

ASN recognizes that sharing this information about patients' care with patients is additional, real work for transplant centers and believes funds should be made available to cover it – and this would be consistent with the overarching goal of IOTA to improve shared decision making. Eventually, when the infrastructure is available through the OPTN (and when the funding mechanisms are finalized, via the cost report or otherwise) this information should be made available to all patients.

Lastly, CMMI requests input on whether sharing of declined offers should be limited to only patients who are “likely to receive an organ offer in the next year.” The society underscores that the vast majority of waitlisted patients receive an offer not only within a year, but within weeks of being waitlisted. (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) ASN recommends that organ offers that are declined that meet the parameters outlined above should be shared with patients (along the lines outlined above).

16. CMMI proposes that IOTA participants would be required to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist.

ASN supports sharing organ offer filter and transplant acceptance criteria with patients. The society recommends that the center's organ offer filters be reviewed with a patient at the time of listing and that patients be updated again if changes are made. For some patients (who desire information about declined offers) their transplant acceptance criteria may be discussed organically periodically as they receive the information about declined offers. For patients who opt out of information about declined offers or who do not engage in dialogue with a center regarding declined offers as the information is shared with them, a re-review annually of organ offer filter and transplant acceptance criteria is likely reasonable (or at re-evaluation, whichever

comes first in a calendar year). ASN supports CMMI's recommendation that patients may also decline this review altogether.

ASN suggests that HHS, HRSA, and the OPTN develop a centralized, standardized way of presenting information about bypass filters to patients in OPTN Transition or Next Gen contracts, obviating the need for centers to convey the information. OPTN already has all the information about centers' bypass filter settings and could make it available to patients via a patient portal or other means on an automated basis, along with standardized information about what certain bypass filter settings mean in a patient-appropriate format. ASN also believes that centralized patient facing education materials ought to be developed by the OPTN or SRTR contractors in a manner that allows them to be leveraged by transplant centers to obviate the need for each program to develop these on their own.

17. CMMI proposes to require IOTA participants to publicly post, on a website, their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist by the end of PY 1.

ASN strongly supports publicly sharing waitlist acceptance criteria. This information is critical to enable patients to make informed decisions about where to seek their care based on their medical and other needs. Certain centers have unique expertise or the ability to accept and transplant more complex patients, yet these important differentiating factors are not presently knowable to patients. Particularly because many patients' insurance will only cover one transplant evaluation workup annually, it is vital that patients have access to information that will better enable them to select the center most likely to accept and transplant them.

As CMMI notes, in addition to the medical aspects of the evaluation, programs also conduct psychosocial and financial evaluations. ASN recommends that criteria related to these aspects of the evaluation also be made publicly available. For example, some programs require fundraising if candidates do not have a minimum bank account balance prior to listing: prospective patients should have access to these parameters.

ASN recommends that a standard format be developed (ideally, by HRSA and the OPTN or SRTR) so that all centers are presenting this information in a uniform fashion. The society also suggests that HHS have HRSA develop (or adopt/modify an existing prototype) a centralized platform that allows patients to compare programs based on these criteria as part of the OPTN Modernization Initiative.

18. CMMI seeks feedback on the proposal to allow an IOTA participant to subsidize the 20 percent coinsurance on immunosuppressive drugs covered by Part B or the Part B-ID benefit and the cost sharing associated with immunosuppressive drugs covered by Part D, when an attributed patient is eligible, meaning the attributed patient does not have secondary insurance and meets the eligibility criteria defined by the IOTA participant and approved by CMS prior to the PY in which the cost sharing support is provided.

In principle, ASN strongly supports CMMI's focus on helping under- or uninsured patients continue to access their immunosuppressive drugs post-transplant—critical to their health and the health of the graft. ASN also concurs with CMMI that people who are under 65 who are 36-months post-transplant may particularly benefit from this kind of support. ASN also recommends that CMMI consider including other essential post-transplant medications, such as anti-virals blood pressure and diabetes medications, and drugs to treat tertiary hyperparathyroidism.

Additionally, CMMI should consider including blood and urine testing to monitor drug toxicity, office visits, and other aspects of care that are not covered under the Part B-ID benefit.

ASN observes that some centers, particularly those that serve large numbers of patients who would be eligible for this benefit, may be the least able to muster the resources to cover the costs of coinsurance and other payments to help patients access these drugs, due to overall low profit margins. This observation underscores the critical importance of increasing the overall upside payment and making it possible for IOTA participants to successfully access those upside payments to cover the costs of things such as the proposed coinsurance or cost sharing on Part B, Part B-ID, and Part D immunosuppressive drugs.

In addition, ASN suggests that CMMI/CMS develop a mechanism by which IOTA participants covering some or all of qualifying patients' coinsurance or cost sharing on Part B, Part B-ID, and Part D immunosuppressive drugs can report that back to CMMI/CMS and have those costs offset in whole or in part. At least three potential models for this concept exist:

- **Costs paid at-cost:** Just as transplant centers receive at-cost payment from CMMI for organ acquisition and other pre-transplant costs related to maintaining transplant readiness (organ acquisition costs), CMMI/CMS could establish a similar cost-reporting mechanism for centers to recoup costs for keeping a graft and transplant recipient healthy through access to immunosuppressive drugs, blood pressure and diabetes medications.
- **Cost-sharing:** A variation on the above concept, under this approach, transplant centers and CMMI would split the costs incurred in covering some or all of qualifying patients' coinsurance or cost sharing on reported Part B, Part B-ID, and Part D immunosuppressive drug costs.
- **Bad Debt:** Just as dialysis organizations can write off 65% of the 'bad debt' from copayments on dialysis care that patients are unable to cover, CMMI/CMS could consider allowing transplant centers to write off a similar percent related to qualifying patients' coinsurance or cost sharing on Part B, Part B-ID, and Part D immunosuppressive drugs, at least mitigating the extent to which these costs come out of their operating budgets.

Lastly, ASN notes that functionally providing this support could present a logistics issue for programs that are not dispensing drugs through a single center but does not believe this is a reason for CMMI not to finalize a version of this proposal.

19. CMMI seeks comment on whether a requirement should be included for IOTA participants to conduct HRSN screening and report HRSN data in a form and manner specified by CMS each PY for their attributed patients. CMMI is seeking input on following the questions in this section, and comment on any aspect of the psychosocial evaluation of waitlisted patients and how this compares to HRSN screenings for the four domains – food security, housing, transportation, and utilities.

ASN appreciates CMMI's interest in collecting this information and concurs that challenges with food security, housing, transportation, and utilities are often direct or indirect barriers to kidney transplantation.

As noted in the proposed rule, these issues are typically covered by social workers as part of the evaluation process, but the information gleaned is not systemically documented across all transplant centers—much less reported to the OPTN registry. However, capturing these kinds of social needs could create opportunities to design meaningful policy interventions. Many, though not all, centers are already capturing this type of information (e.g., Epic SDOH tool, Cerner's PRAPARE tool, etc.). CMMI should work with HRSA and OPTN to include this information in the proposed pre-waitlisting data collection efforts and ensure that this effort aligns with the broader CMS mandate to capture this information at the hospital level.

Supporting this goal, as HHS and HRSA embark upon OPTN Modernization Initiative Transition and Next Gen contracts, the department and agency should work hand-in-glove with the White House-led Gravity Project as well as kidney and transplant professionals to develop a set of data definitions and data standards for EMRs and the OPTN registry. This dataset should include standardized definitions of a limited set of key health-related social needs that are examined as part of the standard evaluation for candidacy. In the future, APIs can and should be developed to support automated collection of these HRSNs from EMRs with minimal additional reporting burden.

Without this critical infrastructure, reporting this data for every patient evaluated could become a tremendous added unpaid burden under the current system. A median 56% of patients who are referred go on to be evaluated, and 20% of patients who are evaluated go on to be waitlisted (<https://estardashboard.shinyapps.io/public/>). While the costs associated with the evaluation in which these data elements would be studied can be added to the cost report for patients who ultimately get transplanted, for patients who do not go on to receive a kidney, the work is unreimbursed. (ASN is not proposing that IOTA attempt to resolve this challenge, but observes that it is a larger systemic issue with the nation's system of kidney transplant reimbursement. Ideally in the future, there would be a mechanism to account for this aspect of kidney transplant care for all evaluated patients.)

ASN also notes that such a data collection effort must also be paired with a plan from HHS to develop and fund interventions to help patients overcome these challenges.

20. CMMI seeks comment on the potential impact of creation of a health equity plan, whether such plans should be voluntary, and whether health equity plans should only be a requirement in later PYs of the IOTA Model.

ASN strongly supports maximizing access to kidney transplantation and ensuring that that access is equitable regardless of socioeconomic status, race/ethnicity, geography, sex/gender, or otherwise. The society sincerely appreciate CMMI's intent with the proposed health equity plan and sees theoretical appeal. As proposed, the concept is well-intentioned but lacks the investment of resources and design rigor that would make the effort likely to yield meaningful results for patients.

One of the greatest strengths of the proposed model is its intensity of focus on increasing access to kidney transplantation, including to populations who have historically had lower levels of access—and the lack of prescription regarding how to achieve those goals. ASN is concerned that, counterintuitively, requiring IOTA participants to conduct initial research, develop and execute a plan, and study and report data back to CMS, as proposed may distract from their ability (and resources) to carry out operational changes that are central to success in IOTA.

CMMI recognizes that a meaningful health equity effort would require resources, as evidenced by the inclusion of the “resource gap analysis,” of “the resources that would be needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant’s current resources that would be needed.” However, absent any support or additional resources, such an effort would likely draw resources from other essential kidney transplant program functions (such as living donor recruitment, patient education and engagement, or long-term follow-up post-transplant care) or be conducted on such a shoestring budget as to have limited scientific rigor and ultimately, minimal effect on patient outcomes.

ASN also notes that a CMMI mandate to collect data that is not collected on a systematic, nationwide (or at least IOTA-wide) basis is probably not a worthwhile effort unless it is done in a systematic manner that allows broad data capture that will inform next steps. In the context of limited resources, CMMI should reserve additional data collection and reporting requirements only when conducted in a manner in which the data are useful beyond a single center to inform nationwide clinical or quality improvement or policymaking.

Lastly, the society notes that the forthcoming pre-waitlisting data collection efforts via both the CMS 2728 form² and through OPTN requirements for transplant centers are likely to yield a bevy of additional information about opportunities to increase equitable access to the waitlist and transplantation, at both nationwide and center-specific levels. Potentially, this information could be used to inform health equity improvement activities in future versions of IOTA, or otherwise. ASN encourages CMMI to partner with HRSA on the development/ and implementation of these data collection efforts as well as the consideration of inclusion of data elements of interest.

21. CMMI seeks comment on the proposed definition of IOTA collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

ASN generally supports the broad list of IOTA collaborators that CMMI proposed and does not have any additional suggestions for the safeguards and requirements outlined. ASN notes that for the model to be appealing to potential collaborators, the upside gains that could be shared with them must be substantial enough to entice their voluntary participation. This reality is another reason the society recommends that CMMI set the maximum upside at approximately double (more than \$15,000) versus the \$8,000 proposed in the original model.

ASN did consider a scenario in which an IOTA collaborator that previously served as a source of referrals for multiple transplant centers opts to collaborate with just a single center, potentially reducing referrals to non-collaborators. However, CMMI does not appear to propose to limit collaboration to just one IOTA participant, which ASN thinks is appropriate: some collaborators may wish to collaborate with more than one IOTA participant. ASN also appreciates CMMI’s emphasis that IOTA collaborator relationships must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care. Ultimately, sources of referral will likely tend to make decisions about where to refer the same way they do today: whichever center they believe has the greatest likelihood of success for their patient

² ASN strongly supported the transplant-related elements contained in the 2728 form updated and shared in July 2024, but continues to believe that other aspects of the form require additional refinement before implementation later in 2024.

22. CMMI is soliciting feedback on the proposal to allow IOTA participants to offer attributed patient engagement incentives in a manner that complies with the restrictions and safeguards in this section.

ASN appreciates CMMI's recognition of the very real barriers many patients—particularly socioeconomically disadvantaged or socially isolated patients who might otherwise be medically good candidates—face to successfully access a kidney transplant. ASN strongly supports waivers for each of the proposed patient engagement incentives. The society also recommends that CMMI add provision of home phlebotomy and home infusion services, which can help minimize costs of coming to the center while still providing high-quality care—practices that were proven successful during the height of COVID-19.

However, similar to the society's recommendations regarding the immunosuppressive drug coinsurance or copayment offset waiver, ASN strongly recommends that CMMI identify a mechanism by which to help IOTA participants offset the cost of providing these benefits in whole or in part.

23. CMMI is interested in receiving comments on the extent to which dental issues emerge once an individual has been listed for a kidney transplant and whether we should consider dental services as an attributed patient engagement incentive under the auspices of the IOTA Model.

Dental issues and related infections can derail the transplant process used – especially by dental providers who are often not Medicare enrolled. ASN supported efforts by CMS in November 2022 when it issued a rule (CMS-1770-F) clarifying that Medicare payment may be made for dental services that are “inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service.” The agency indicated that payment could be made for medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with a transplant.

Medicare billing and reimbursement for this medically necessary dental care depends upon coordination and exchange of information (and in some cases, payment arrangements) between the patients' medical and dental providers. Both practitioners would need to be enrolled in Medicare and meet all other requirements for billing. Alternatively, a non-participating dental provider could perform the dental services under an arrangement with a Medicare-participating physician, who may submit the claim for Medicare payment and reimburse the dental provider pursuant to the arrangement.

It is not clear if this change is widely known or used – especially by dental providers who are often not Medicare enrolled. ASN believes that access to dental care is essential to the transplant pathway and is seeking clarification on the level of usage of this policy. Dental issues seldom impact transplant-readiness unless required by an insurer. On the other hand, requiring dental services frequently creates an additional barrier for patients to become transplant-ready. ASN strongly supports more clarification and a waiver.

24. In addition to the proposed measures the IOTA Model proposes would be used, CMMI would consider incorporating a measure of HRQOL and access to waitlist. CMMI seeks comments on the inclusion of a HRQOL patient-reported outcome measure in the IOTA Model, as well as on the inclusion of an access to waitlist measure. CMMI is also seeking input to the questions later in this section, and comment on any aspect of a kidney transplant recipient patient experience

measure that should be included in a new measure or existing and validated measurement tools and instruments appropriate for use in the IOTA Model.

ASN appreciates CMMI's interest in a patient-reported outcome measure (PROM) on health-related quality of life in the context of kidney transplant especially given the relative paucity of measures of quality of care for kidney transplant. No currently validated PROMs of quality of life exist, much less any PROMs that are appropriate for use in the IOTA Model. (Ju A, Chow BY, Ralph AF, Howell M, Josephson MA, Ahn C, et al. Patient-reported outcome measures for life participation in kidney transplantation: A systematic review. *Am J Transplant*. 2019;19(8):2306-17. PMID: 30664327) However, ASN is strongly supportive of the development of such a PROM, provided it is rigorously tested and developed using the highest standards. Without a firmly evidence-based metric, everyone—patients, transplant professionals, payers, and others—risks a significant administrative burden for no meaningful gain. At the same time, as the U.S. collectively pushes the envelope in terms of use of more marginal organs and more complex patients, it will be more important than ever to ensure the nation's transplant system is delivering patients the quality of life they seek as a result. Having a PROM to help assess that goal will be more important than ever.

In terms of the most important aspects of quality of life (QOL) to include in such a PROM, ASN would largely defer to the input of patients, patient organizations, and families and caregivers to define what is most important in terms of their quality of life. However, ASN notes that return to work is an oft-discussed, but less often attained, facet of quality of life that could be considered in consultation for inclusion in a PROM with the aforementioned stakeholders. The Standardized Outcomes in Nephrology-Kidney Transplantation has published some research on meaningful themes for patients and families that could help inform future efforts. (Ju A, Chow BY, Ralph AF, Howell M, Josephson MA, Ahn C, et al. Patient-reported outcome measures for life participation in kidney transplantation: A systematic review. *Am J Transplant*. 2019;19(8):2306-17. PMID: 30664327)

25. CMMI seeks input on a potential access to waitlist measure

ASN appreciates CMMI's interest in the waitlist (and referral and evaluation) process as a potential area for improved understanding of as well as patient access to kidney transplantation. At present, no existing measures are currently being used on a nationwide basis to measure access to the waitlist. As CMMI is aware, a substantial body of literature examining access to waitlisting and related aspects of care exists, particularly, on a regional basis. As described in this literature, researchers have designed waitlist-related metrics for different entities with roles to play in the process and conducted internal validation. (Paul S et al. Kidney transplant program waitlisting rate as a metric to assess transplant access. *Am J Transplant*. 2021 Jan;21(1):314-321; Paul S et al. Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. *CJASN*. 2018 Feb 7;13(2):282-289)

Indeed, the fact that multiple stakeholders have a role in the waitlisting (and referral and evaluation) process heightens the importance of measuring aspects of the process that are within the control of the entity being measured. However, ASN notes that there has been a rapid shrinking of the national waitlist since the introduction of KAS 2014 and the subsequent introduction of a waitlist mortality measure by the OPTN as a regulatory oversight measure, underscoring the risks of unintended consequences.

ASN is aware and enthusiastically supportive of efforts underway at CMS (via the 2728) to collect information on referrals made by dialysis providers, as well as efforts underway at HHS and HRSA to collect information on referrals received, key data points in the evaluation process, and whether patients are ultimately waitlisted from transplant centers. These are promising efforts that, if harmonized in terms of the data elements collected and data specifications used, could lay the foundation for more uniform understanding and assessment of waitlisting access nationwide, selectivity of transplant centers, understanding of the challenges that patients face in accessing the waitlist while also helping to identify areas for improvement/intervention.

In this vein, such standardized data elements and data specifications are also essential to be developed and adopted into EMRs, allowing for the data to be transmitted to OPTN/ CMS in a way that minimizes additional burden to transplant hospitals. Having high-quality data and having the ability to supplement this data from multiple sources is imperative to ensure that the datasets are robust, reliable and accurate before any waitlisting (or other) metrics can serve their intended purpose.

Overall, ASN believes that based on the preponderance of evidence suggesting a high level of variation in access to waitlisting and waitlisting practices nationwide, developing a measure of waitlist access among those referred for transplant would be reasonable. Again, it would be imperative for such a measure(s) to be developed using the highest standards, appropriately risk-adjusted, and rigorously tested prior to implementation. The society cautions that this measure(s) should be used for quality improvement, not punitive, purposes, particularly in the early years. Aligned with the CMS approach to collecting 'reporting' variables in dialysis, ASN believes a reporting-only, non-punitive approach would be optimal. ASN also recommends that adoption of such a measure may be done more appropriately on an OPTN-wide basis, rather than an IOTA-only basis. ASN is particularly interested in process measures such as "time to..." metrics, such as time to referral to waitlist, time from referral to waitlist and time from waitlist to transplant. Such measures have been utilized in quality improvement reporting for more than 30 transplant centers for multiple years (<https://estardashboard.shinyapps.io/public/>) and highlight tremendous variation across centers, suggesting these are important targets for monitoring.

The society is also cognizant of concerns about such a measure(s) being gamed, and of unintended consequences of such a measure(s); as with any potential measure, these are valid and important concerns to weigh and assess during the development process.

IOTA and the Transplant Nephrology Workforce

As noted earlier, while being fully supportive of IOTA's goals, ASN is concerned about the availability of transplant nephrologists to care for patients amidst efforts to grow patients access to transplantation. **Appendix 4** details the contrast in the number of transplant nephrologists available to care for kidney transplant patients as compared to other organ transplant recipients.

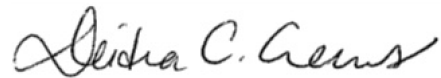
ASN, together with the American Society of Transplantation, is pursuing ACGME accreditation for transplant nephrology—one step ASN hopes will begin to alleviate the shortage. If successful, is pursuing Accreditation Council for Graduate Medical Education (ACGME) accreditation will enable CMS and CMMI to identify transplant nephrologists in the CMS Provider Enrollment, Chain, and Ownership system (PECOS). Potentially, this could facilitate the development of unique transplant nephrology RVU codes and/or the identification of the unique contributions of transplant nephrologists in future value-based care models.

As described throughout this comment letter, much of the essential work that transplant nephrologists perform today, and that will increasingly need to be performed to succeed in reaching IOTA's goals, is not patient-facing and is frequently not reimbursable. ASN is optimistic that accreditation will ensure nationwide adoption of uniformly rigorous transplant nephrology training, increase interest in transplant nephrology as a career, help secure better access to the expertise of transplant nephrologists and the care they provide for all communities, and enable the vital contributions of transplant nephrologists to kidney transplant care to be fully recognized and appropriately valued in future value-based care models. ASN is interested in CMMI's perspective on the role of ACGME accreditation in future models.

Conclusion

In conclusion, ASN commends CMMI for proposing IOTA and strongly supports its aim to increase patient access to kidney transplantation. The society hopes the recommendations contained in this comment letter are helpful, and we stand ready to provide any additional input CMMI would find useful as it advances IOTA. In particular, ASN would be pleased to discuss the calculations and the appendices that support our recommendations. ASN Strategic Policy Advisor to the Executive Vice President Rachel N. Meyer can be reached at rmeyer@asn-online.org and ASN Regulatory and Quality Officer David L. White can be reached at dwhite@asn-online.org.

Sincerely,

A handwritten signature in black ink that reads "Deidra C. Crews". The signature is written in a cursive, flowing style.

Deidra C. Crews, MD, ScD, FASN
President

Appendix 1. CMMI Proposed (Table A and Table B) vs. ASN Alternative (Table C and Table D) Growth Rate Goals and Historic Growth Rates (Table E) and Financial Implications (Table F)

	A	B	C	D	E	F	G	H	I	J	K	M	N	O	P	Q
1	TABLE A										Kidneys attributable to IOTA at a SINGLE center					
2	Best Baseline number of transplants		100													
3	National Growth Rate		10%													
4	Column1	Column2	PY1	PY2	PY3	PY4	PY5	PY6	Total	Total	Annualized	Annualized Effective growth rate				
5	Baseline Growth		110	121	133	146	161	177								
6	Meeting 150% of transplant target		165	272	449	741	1223	2018	4020	361786	60298	165%				
7	Meeting 125% of transplant target		138	189	260	357	491	676	1263	113628	18938	138%				
8	Meeting 120% of transplant target		132	174	230	304	401	529	921	82876	13813	132%				
9	Meeting of 115% of trnsplant target		127	160	202	256	324	410	630	56701	9450	127%				
10	Metting of 110% of transplant target		121	146	177	214	259	314	383	34508	5751	121%				
11	Meeting 105% of transplant target		116	133	154	178	206	237	175	15766	2628	116%				
12	Meeting 100% of transplant target		110	121	133	146	161	177	0			110%				
13	Meeting 75% of transplant target		91	100	110	121	133	146	-149			83%				
14	TABLE B															
15	National Growth Rate		5%													
16	Column1	Column2	PY1	PY2	PY3	PY4	PY5	PY6	Total	Total	Annualized	Annualized Effective growth rate				
17	Baseline Growth		105	110	116	122	128	134								
18	Meeting 150% of transplant target		158	248	391	615	969	1526	3193	287374	47896	158%				
19	Meeting 125% of transplant target		131	172	226	297	389	511	1013	91158	15193	131%				
20	Meeting 120% of transplant target		126	159	200	252	318	400	740	66634	11106	126%				
21	Meeting of 115% of trnsplant target		121	146	176	213	257	310	508	45692	7615	127%				
22	Metting of 110% of transplant target		116	133	154	178	206	237	310	27873	4645	116%				
23	Meeting 105% of transplant target		110	122	134	148	163	180	142	12765	2127	110%				
24	Meeting 100% of transplant target		105	110	116	122	128	134	0			105%				
25	Meeting 75% of transplant target		87	68	54	42	33	26	-404			83%				
26																
27	TABLE C															
28	ASN Proposal: % Growth on National Growth Rate															
29	Best Baseline number of transplants		100													
30	National Growth Rate		10%													
31	Column1	Column2	PY1	PY2	PY3	PY4	PY5	PY6	Total	Total	Annualized	Annualized Effective growth rate				
32	Baseline Growth		110	121	133	146	161	177								
33	Meeting 150% of transplant growth rate		115	132	152	175	201	231	158	14217	2369	115%				
34	Meeting 125% of transplant growth rate		113	127	142	160	180	203	76	6826	1138	112.5%				
35	Meeting 120% of transplant growth rate		112	125	140	157	176	197	60	5417	903	112.0%				
36	Meeting of 115% of trnsplant growth rate		112	124	139	155	172	192	45	4030	672	111.5%				
37	Metting of 110% of transplant growth rate		111	123	137	152	169	187	30	2665	444	111.0%				
38	Meeting 105% of transplant growth rate		111	122	135	149	165	182	15	1322	220	110.5%				
39	Meeting 100% of transplant growth rate		110	121	133	146	161	177	0			110.0%				
40	Meeting 75% of transplant growth rate		108	116	124	134	144	154	-70			107.5%				
41	TABLE D															
42	National Growth Rate		5%													
43	Column1	Column2	PY1	PY2	PY3	PY4	PY5	PY6	Total	Annualized	Annualized Effective growth rate					
44	Baseline Growth		105	110	116	122	128	134								
45	Meeting 150% of transplant growth rate		113	121	130	140	151	162	103	9312	1552	107.5%				
46	Meeting 125% of transplant growth rate		112	119	126	134	142	151	69	6201	1033	106.3%				
47	Meeting 120% of transplant growth rate		111	118	125	133	141	149	62	5594	932	106.0%				
48	Meeting of 115% of trnsplant growth rate		111	117	124	131	139	147	55	4991	832	105.8%				
49	Metting of 110% of transplant growth rate		111	117	123	130	137	145	49	4394	732	105.5%				
50	Meeting 105% of transplant growth rate		111	116	122	129	136	143	42	3802	634	105.3%				
51	Meeting 100% of transplant growth rate		110	116	122	128	134	141	36			105.0%				
52	Meeting 75% of transplant growth rate		109	113	117	122	126	131	4			103.8%				
53																

	A	B	C	D	E
1	TABLE E.				
2		All Kidney transplants	National Growth Rate	Deceased donor Kidney transplants	DDKT National Growth Rate
3	2018	16,310		9,867	
4	2019	18,018	10.5%	11,152	13.0%
5	2020	17,159	-4.8%	11,925	6.9%
6	2021	19,186	11.8%	13,215	10.8%
7	2022	20,089	4.7%	14,227	7.7%
8	2023	21,764	8.3%	15,471	8.7%
9	2024*	22,600	3.8%	16,282	5.2%
10					
11		Median Growth Rate	6.5%		8.2%
12		Average Growth Rate	5.7%		8.7%
13					

Appendix 1 Table F. Financial Implications of CMMI Proposed Growth Rates to a Baseline-100 Transplant Program

Program year	PY1	PY2	PY3	PY4	PY5	PY6		Total
Number of transplants performed (baseline = 100)	165	272	449	741	1223	2018		
Number of Medicare FFS transplants	41	68	112	185	306	504		
Incentive payment for full achievement	0	\$ 330,000	\$ 544,500	\$ 898,425	\$ 1,482,401	\$ 2,445,962	\$ 4,035,837	\$9,737,125

For a transplant center that at baseline performs 100 transplants, with approximately a quarter of them being Medicare FFS transplants, 150% multiplier applied to the transplant target with a national growth rate of 10% would result in an exponential rate of growth expectation as outlined in the table above. As a result, the total incentives from IOTA to a single transplant center at \$8,000 per Medicare Fee for Service transplant would be

a cumulative of \$9.74 million over the course of 6 years. While ASN does not believe that this growth rate is achievable or sustainable, the society also does not believe CMMI intended to propose an incentive of this size in the model for an individual transplant center.

Appendix 2. Program Growth 2021-2022 and 2022-2023 By Program Size

Appendix 2A. Program Growth 2021-2022 By Program Size

Center volume = 11-50

Variable	N Centers	Mean % Change	SD	50 th percentile	25 th percentile	75 th percentile	Min	Max
Pct_chg_t~22	77	13.6	52.3	8.3	-21.2	33.3	-58.8	235.1

Center volume = 51-200

Variable	N Centers	Mean % Change	SD	50 th percentile	25 th percentile	75 th percentile	Min	Max
Pct_chg_t~22	92	5.5	21.0	3.3	-7.2	14.1	-30.8	106.8

Center volume = >200

Variable	N Centers	Mean % Change	SD	50 th percentile	25 th percentile	75 th percentile	Min	Max
Pct_chg_t~23	43	-0.7	13.1	.3	-11.0	7.7	-24.6	25.2

Center volume change between 2021 and 2022 broken out by volume (11-50 transplants [76 programs]; 51-200 transplants [92 programs], and >200 transplants [43 programs]). Median volume shift ranged from 2% to 10% growth. Unsurprisingly, there was greater percentage change volatility for smaller programs. but up to nearly 20% fewer at the 25th percentile and nearly 30% more at the 75th percentile for the smallest volume centers, while the largest centers appeared more stable, with ~5% fewer at the 25th percentile and 13% more at the 85th percentile.

Appendix 2B. Program Growth 2022-2023 By Program Size

Center volume = 11-50

Variable	N Centers	Mean % Change	SD	50 th percentile	25 th percentile	75 th percentile	Min	Max
Pct_chg_t~23	76	7.4	38.3	2.0	-19.4	28.6	-95.8	100

Center volume = 51-200

Variable	N Centers	Mean % Change	SD	50 th percentile	25 th percentile	75 th percentile	Min	Max
Pct_chg_t~23	92	11.0	26.5	9.6	-7.3	22.5	-48.0	105.5

Center volume = >200

Variable	N Centers	Mean % Change	SD	50 th percentile	25 th percentile	75 th percentile	Min	Max
Pct_chg_t~23	43	5.2	13.0	3.5	-4.6	13.6	-23.1	36.6

Center volume change between 2022 and 2023 broken out by volume (11-50 transplants [76 programs]; 51-200 transplants [92 programs], and >200 transplants [43 programs]). Similar volume change trends by program size patterns are seen in this calendar year, with smaller programs experiencing greater shifts in volume and larger programs appearing more stable.

Appendix 3. Financial Performance Scenarios

	A	B	C	D	E	F	G	H	I	
			incentive	PY1	PY2	PY3	Y4	Y5	y6	
1										
2		total Txp		200	220	242	266	293	322	
3		Medicare txp		50	63	78	98	122	153	
4	Expected Incentives/penalties (Assuming 50 Medicare Tx per year)*	Scenario A	8,000	0	400,000	500,000	625,000	781,250	976,563	
5		Scenario B	4,000	0	200,000	250,000	312,500	390,625	488,281	
6		Scenario C	-2,000	0	-100,000	-125,000	-156,250	-195,313	-244,141	
7		Scenario D	7,500	0	375,000	468,750	585,938	732,422	915,527	
8		Scenario E	15,000	0	750,000	937,500	1,171,875	1,464,844	1,831,055	
9										
10	Expected Costs									
11		Clinical Coordinators (2)		286,000	300,300	315,315	331,081	347,635	365,017	
12		Medical Director (0.1 FTE)		30,000	31,500	33,075	34,729	36,465	38,288	
13		Patient Navigator (1)		71,500	75,075	78,829	82,770	86,909	91,254	
14		Txp Nephrologist	350000					350,000	350,000	
15										
16		Costs		387,500	406,875	427,219	448,580	471,009	494,559	
17		Costs with OACC (50%)		193,750	203,438	213,609	224,290	235,504	247,280	
18		Costs with OACC (50%) and txp nephrology		193,750	203,438	213,609	224,290	585,504	597,280	
19										
20	Operating Margin	Scenario A		-387,500	-6,875	72,781	176,420	310,241	482,003	
21		Scenario B		-387,500	-206,875	-177,219	-136,080	-80,384	-6,278	
22		Scenario C		-387,500	-506,875	-552,219	-604,830	-666,321	-738,700	
23		Scenario D		-387,500	-31,875	41,531	137,358	261,413	420,968	
24		Scenario E		-387,500	343,125	510,281	723,295	993,835	1,336,496	
25										
26	with OACC accounted for	Scenario A		-193,750	196,563	286,391	400,710	545,746	729,283	
27		Scenario B		-193,750	-3,438	36,391	88,210	155,121	241,002	
28		Scenario C		-193,750	-303,438	-338,609	-380,540	-430,817	-491,420	
29		Scenario D		-193,750	171,563	255,141	361,648	496,918	668,248	
30		Scenario E		-193,750	546,563	723,891	947,585	1,229,339	1,583,775	
31										
32	Additional Txp nephrologists	Scenario A		-193,750	196,563	286,391	400,710	195,746	379,283	
33		Scenario B		-193,750	-3,438	36,391	88,210	-194,879	-108,998	
34		Scenario C		-193,750	-303,438	-338,609	-380,540	-780,817	-841,420	
35		Scenario D		-193,750	171,563	255,141	361,648	146,918	318,248	
36		Scenario E		-193,750	546,563	723,891	947,585	879,339	1,233,775	
37										
38										
39	*200 Transplants per year (of which 50 are medicare), 25% increase from base year: PY 1(50), PY2 (63), PY3 (78)									
40	Scenario A: Maximum incentive achieved									
41	Scenario B: Incentive of \$4000\$ per kidney transplant									
42	Scenario C: Penalty of \$2000 per kidney transplant									
43	Scenario D: Incentive of \$7500 per kidney transplant, assuming max incentive of 15,125 as proposed by ASN									
44	Scenario E: incentive of \$15000 per kidney									

Appendix 4. Transplant Nephrology Workforce

Transplant Specialist Type	# of Physicians	New Transplants in 2023	Wait-listed Patients in 2023	Prevalent Patient Population in 2023	New Transplant Physician Ratio	Wait-listed Patients Physician Ratio
Transplant Pulmonologists	~250	3026 (lung)	943 (lung)		12	4
Transplant Hepatologists	826 (valid ABIM certificates)	10,660 (liver)	9870 (liver)		13	12
Transplant Cardiologists	1441 (valid ABIM certificate)	4545 (heart) 54 (heart lung)	3361 (heart) 40 (heart-lung)		3	2
Transplant Nephrologists	800 (AST data)	27,332 (kidney) 912 (pancreas)	88,760 (kidney) 2841 (pancreas)	>250,000 (kidney) 15,000 (pancreas)	35	114

Data: OPTN, AST, ABIM.

