AMERICAN SOCIETY OF TRANSPLANTATION

July 15, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Submitted Electronically

Re: [CMS-5535-P]; RIN 0938-AU51; Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (IOTA Model Proposed Rule)

Dear Administrator Brooks-LaSure:

The American Society of Transplantation (AST), which represents more than 5,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care, appreciates the opportunity to provide feedback on the Request for Information entitled, "Alternative Payment Model Updates and Increasing Organ Transplant Access (IOTA) Model" issued by the Centers for Medicare & Medicaid Services (CMS).

AST appreciates and supports the intent behind the proposed CMS model to promote greater care coordination, increase deceased donor kidney utilization, improve patient outcomes, and provide equitable access to kidney transplants**. However, AST recommends that IOTA not be implemented as proposed based on concerns about operational challenges, adverse financial impacts, and potential disruptions to transplant patient care that may result from IOTA**.

AST and its member experts have been and continue to be strong partners with CMS and state and federal entities working to optimize transplantation. The Society's

AST NATIONAL OFFICE
1000 Atrium Way, Ste 400 • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.581.9604
info@myAST.org • myAST.org

GOVERNMENT RELATIONS
William Applegate, Director of Government Relations
Polsinelli
1401 I Street NW, Ste: 800 • Washington, DC 20004
202.258.4989 • bapplegate@polsinelli.com

members are working tirelessly to improve the field at both the patient and system level. As we advance these efforts, AST encourages CMS to consider that placement of higher-risk organs requires greater effort and more manpower that is not reflected in reimbursement under IOTA or other payment models. This concern is heightened by changes that CMS is considering to the organ acquisition cost policy. If implemented, changes to that policy would have a substantial impact on reimbursement that could be exacerbated by the IOTA payment model. Further, other recent changes have dramatically increased the costs of transplantation without commensurate increases in reimbursement. Therefore, AST fears that the IOTA proposal would compound that financial strain on transplant centers and transplant physicians.

AST's concerns focus on five primary areas as described in this letter. These concerns include the:

1. **selection of transplant hospitals and determination of baseline metrics,**
2. **timeline for IOTA,**
3. **selection and weighting of performance score metrics,**
4. **health equity strategy, and**
5. **resources needs and financial incentives.**

Selection of Transplant Hospitals and Determination of Baseline Metrics

Program Selection: AST encourages CMS to reconsider using a geography-based framework to determine which transplant centers will be required to participate in the IOTA model. Such an approach conflicts with the Agency's directives to move away from these measures in order to enhance equity and efficiency in the organ transplant system. Instead, AST suggests that CMS consider national distribution models and data-driven approaches to ensure that efforts to increase transplantation are based on patients' medical needs and the likelihood of successful outcomes. For example, kidney transplant programs within a donor service area (DSA) are more likely to serve communities and patients with similar social determinants of health (SDOH). Patients in these DSAs are treated by shared community nephrologists and dialysis units and these patients face similar barriers in accessing transplant centers and resources to mitigate SDOH. Thus, CMS might consider establishment of control groups within the same geographical area as a more valid standard to gauge performance improvements.

Baseline Metrics: Small transplant programs (i.e., those performing more than 11 transplants a year in the previous year) that are mandated to IOTA participation are disadvantaged in their potential for growth in volume as these centers most often do not meet the volume requirements for Centers of Excellence (COE). These non-COE kidney programs will not have the contracts with Medicare or Medicaid Replacement products, Employer Group Health Plans, or Affordable Care Act plans that larger programs have, which will impede their ability to meet growth metrics.

Further, due to cohorting and data lags, there is up to an 80 percent overlap in outcomes in program summary reports. The IOTA proposal should include an adjustment to the transplant target rate for those kidney transplant programs with payer contract terminations to include loss of COE designation(s) during the model term

because the loss of payor contracts and/or COE designation results in substantial volume reductions and barriers to transplant referrals and evaluations. Consideration is also needed for startup programs that do not yet meet COE criteria.

Timeline for IOTA

***Initiation**:* AST is concerned that the rapid initiation and short runway for IOTA may present significant challenges for transplant programs in securing the necessary resources to meet program criteria. AST proposes that CMS delay implementation of the model by 6 to 12 months to enable transplant hospitals to budget for, and to put in place the prerequisite infrastructure that will be needed for the model to derive its intended benefits.

***Model Duration**:* AST seeks clarification from CMS on the rationale for selecting six years as the model duration. The long duration is concerning due to uncertainties around potential changes to CMS reimbursement for organ acquisition costs and other concurrent changes affecting the field. Instead, AST proposes that a more feasible model would be a 12- to 18-month pilot initiation project starting January 1, 2025 (or later as proposed above), with CMS working with selected programs to align scores with improvement efforts, assess resource needs, and develop workflows, tracking, and reporting mechanisms. During the pilot testing period, scores should not count toward the final payment calculation scorecards.

In addition, AST recommends the IOTA proposal be modified such that IOTA will be suspended at any time during the mandatory period should CMS change the organ acquisition methodology as initially proposed in the Fiscal Year 2021 Health Insurance Prospective Payment System or as refined in the Fiscal Year 2023 Hospital Outpatient Prospective Payment System. This is necessary given the unintended consequences of that proposed change as outlined in AST's public comments to the Agency, including in a joint letter from AST and the American Society of Transplant Surgeons in response to a CMS request for information. Lastly, AST expects that evaluation of program effectiveness would be needed much earlier than the conclusion a six-year program.

***Standard Provisions**:* Clarification is needed on the "standard provisions" that will apply to all CMS Innovation Center models starting on or after January 1, 2025.

Selection and Weighting of Performance Score Metrics

Achievement Domain: The reliance on improvement over baseline performance rather than absolute performance punishes programs that have already overachieved and rewards those that have fallen behind. Many transplant centers have – at significant effort and great cost – increased their performance in recent years. Further, many such programs will have taken greater outcomes risk in so doing that may affect their ability to further take unadjusted risk and may have affected their eligibility for payor COE status or drawn regulatory scrutiny. Such direct adverse treatment of the very programs who have led the way on expanding kidney transplant runs counter to the goals of this proposal and should not remain in any final proposal.

The **thresholds** for increasing transplant rates—which represents 60 points of the overall score—are aggressive such that they could negatively impact performance score metrics for all programs. For example, to achieve a 10 percent increase in kidney transplants, a large-volume transplant center performing over 400 transplants annually would need to perform an additional 40 transplants per year. While the absolute number for smaller programs would be less, any additional transplants per year may strain personnel and infrastructure. Appropriate lead time is necessary to estimate the increase in transplant volume so that programs of any size can accommodate the increased volume. Infrastructure related to increasing transplant volume, particularly higher risk candidates and donor organs is significant. At the 2024 Transplant Management Forum, a survey conducted with 140 transplant leaders found that the need for “space” was ranked as one of the top barriers to increasing transplantation. Notably, these leaders highlighted operating rooms, hospital beds, and even office space as substantial constraints. Other infrastructure needs are wide-ranging and include infusion bays, access to inpatient and outpatient dialysis for higher volumes of recovering recipients with delayed graft function, and additional personnel such as nephrologists, surgeons, medical kidney pathologists, transplant psychiatrists, infectious disease physicians, clinical laboratory specialists and technicians, transplant administrators, post-transplant advanced practice providers, nurse coordinators, transplant pharmacists, dieticians, and social workers, among others. Such an investment may thwart a participating center's ability to meet mandated targets, and disregarding additional infrastructure needs would put additional stress on the healthcare system. For all these reasons, AST recommends that the achievement threshold is lowered to a more realistic performance metric (e.g., 110 to 125 percent relative to transplant target.)

As an alternative approach, building on AST’s earlier proposal for a 12- to 18-month pilot initiation project, the Center for Medicare and Medicaid Innovation could use this time to determine realistic growth targets. The use of incremental growth targets could provide yet another alternative. However, this incremental approach would require significant study by CMS to determine the mechanism best suited to achieve the goals of IOTA. Determining such a mechanism is beyond the scope of AST’s comments at this time.

AST also recommends that CMS consider separating activity and growth into two categories to measure growth in live donation apart from growth in deceased donation to incentivize growth in both domains, given that these areas require substantially different operational strategies and require different resources.

For a **baseline metric**, AST recommends the exclusion of Calendar Year (CY) 2021 activity in the determination of “participant-specific target” for performance year 1. Different regions of the United States were affected by COVID-19 at various times. Therefore, data from CY 2021 have the potential to unintentionally decrease or increase baseline performance, thereby occluding the true performance of programs mandated to participate in the IOTA model. Furthermore, the Organ Procurement and Transplantation Network (OPTN) KAS 250 policy was implemented in CY 2021, moving from a system where most deceased donor kidneys were prioritized for candidates

within the same DSA, to one where priority is based on distance between the candidates' transplant center relative to the donor hospital. While this new policy served to reduce pre-existing geographic disparities in kidney transplantation and mitigate performance variability between organ procurement organizations that serve DSAs, it also resulted in substantial changes in organ offers and transplant rates for many centers compared to pre-KAS 250 implementation. For these reasons, AST believes that 2022 and 2023 are more appropriate years on which to base historic performance for this domain.

***Efficiency Domain**:* AST requests clarification as to whether CMS is proposing to use the existing Scientific Registry of Transplant Recipients (SRTR) organ acceptance rate or if the Agency intends to develop a new metric. AST advises caution in introducing new risk models for organ offers prior to those models undergoing peer-reviewed validation. In addition, it is unclear whether a program's utilization of organ offer filters will be the driver of this measure rather than the actual acceptance rate for each program. Would programs that are already high-filter users be penalized or rewarded? In other words, is high filter usage a measure of efficiency, quality, or both? CMS should consider how to ensure a level playing field between programs who have previously adopted filters and newly mandated programs who will receive higher scores for this domain during year one due to their first-time implementation of filters that have already been employed by other programs.

***Quality Domain**:* AST is concerned that the proposed measures (which are based on the CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, Three-Item Care Transition Measure, and a post-transplant composite graft survival rate measure) may not align with current practices and could require additional resources without realizing significant patient benefit. Example concerns are provided below. Further, CMS should provide clarity on the required survey tools and how improvements or scores will be weighted. In addition, will there be excluded patients, such as those with a high panel reactive antibody test, re-transplanted patients, or safety-net kidney recipients? Clarity is also needed on what CMS means by "attributed patients."

CollaboRATE scores: Clarity is needed on when and which patients will be surveyed. Of note, use of CollaboRATE may be more useful in the outpatient setting where a multitude of decisions are made on medications, dialysis, and other treatments. Further, initial research has shown that CollaboRATE scores should be adjusted based on patients' age, health status, gender, race, and language spoken at home, as well as the mode of survey response.1[i] Patient health care provider racial concordance may also impact scores. Lastly, this tool has not been validated in the transplant patient population.

Organ Declines: CMS has proposed that IOTA participants inform patients on the waitlist, every month, of the number of times an organ offer was declined on each patient's behalf and reason(s) why each organ was declined. It is unclear if this notification applies only to primary organ offers, or to all organ offers. In either instance, operationalizing this monthly requirement for each patient could—depending on a program's offer volume—require additional FTE coordinators or otherwise burden the operations of procurement teams in the transplant center. Further, this patient

engagement must be carefully designed and implemented so that it avoids confusion and supports patient decision-making. In the absence of an evidence-based communication program, CMS should allow programs flexibility in the timing and approach to managing these discussions. For example, transplant programs and patients may prefer the use of patient health portals (such as MyChart) to document primary organ offers and reasons for decline. Patients will have access to information essentially in real time and can readily submit questions to the team through their portal. Given that patients' access to their health care information is already mandated, the creation of a secondary process is unnecessary and overly cumbersome.

Lastly, AST would like to emphasize that requiring each transplant program to develop such a reporting system may be considerably less efficient than directing the OPTN to develop a patient portal that allows patients to view their own offer filters and organ decline statistics online. This would promote engagement by those patients and promote education and accountability at transplant centers, as patients would be able to see information themselves. This would be both more efficient and more effective in achieving the desired result.

Cancer screening: The vast majority of kidney transplant programs do not have the resources to function as a primary care practice for their patients, nor do they have the experience and expertise of primary care practices. Patients are counseled on the importance of cancer screening, especially for skin cancer, but they are typically advised to follow-up with their primary care providers for all general health maintenance. While AST appreciates the intent of including the colorectal cancer screening measure in the model, we suggest that this is a measure that is more appropriate in the primary care sphere than as a transplant-related measure, especially because rates of colon cancer are similar between kidney transplant and non-transplant patients. On the other hand, skin cancer has a far higher prevalence in transplant patients compared to the non-transplant population. Therefore, AST proposes that there would be more value in creating a measure related to skin cancer screenings.

Graft and patient survival outcome measures: AST believes that increasing transplant efficiency and numbers must be appropriately balanced with other outcomes. Increasing the number of transplants should not come at the cost of shorter graft survival. Further, AST believes that the CMS proposed outcome measure—calculated as the total number of functioning grafts divided by the total number of kidney transplants in year 1 and then calculated as a composite measure over subsequent plan year—is not a reasonable replacement for the current gold standard for outcome measures. AST requests a rationale for CMS' decision not to use the existing SRTR survival models. For example, AST is concerned about the lack of adjustments for co-morbidities and a defined roll-off time. Currently, transplant center performance is monitored utilizing a rolling 2.5-year cohort. Measurements include wait-list mortality, kidney graft survival, and patient mortality at various post-transplant intervals. This SRTR model represents the most statistically sound outcomes measurement and an appropriate way to compare large and small programs. Any risk-adjusted survival metric should be one that the SRTR creates and maintains.

Risk Mitigation Measures*:* CMS should incorporate risk mitigation measures into the outcome metrics. To achieve higher transplant rates, programs will need to use more hard-to-place donor organs, which may increase the rates of delayed graft function (DGF) and subsequently the cost of patient care for those experiencing DGF. The IOTA model should address how these risks will be mitigated, or how transplant centers will be rewarded for accepting higher risk organs to increase transplants performed and decrease organ non-utilization rates. CMS should also evaluate and remedy dialysis reimbursement and access restrictions to ensure patients with delayed DGF post discharge have access to dialysis until DGF is resolved.

AST recognizes that three kidney transplant DRG codes (650, 651 and 652) now exist based on the presence or absence of a major medical complication/comorbidity and/or requirement for dialysis. However, it is unclear whether this payment sufficiently accounts for the expected incremental costs related to hard-to-place organs (i.e., those at the highest risks for DGF, primary non-function, and graft loss) into the most medically complex patients (e.g., those at the highest risk for medical complications, graft loss and death). Given that kidney transplant is already a low-margin procedure, AST is concerned that further changes that are financially detrimental could make it sufficiently unfavorable for hospitals that they elect not to put additional resources into it, or even close programs.

Recent data indicate that 35 to 40 percent of hospital kidney transplant admissions were reimbursed at the DRG codes with higher levels of reimbursement (primarily 650) in FY 2021 and FY 2022.[ii] Compared to the base DRG 652 with neither dialysis nor a major medical complication (reimbursed at approximately $34,000), DRG 651 (kidney transplant with dialysis) and DRG 650 (kidney transplant with dialysis and major complication/comorbidity) are reimbursed at approximately $8,000 and $17,500 more, respectively. Under the IOTA model, it is likely that the majority of incremental transplants will be at DRG codes 650 and 651. Since DRG 650 accounted for over two-thirds of transplants reimbursed at the higher DRG codes, we believe that the proposed incentive of $8,000 falls short of offsetting the increased cost of transplanting more hard-to-place kidneys into higher risk transplant recipients. Based on the anticipated distribution of the increased kidney transplant volume, we would anticipate that an upside incentive between $13,000 to $15,000 would be more appropriate. AST recognizes that under this approach there may need to be a scaled-up increase in the downside risk as well.

Support for Living Donor Programs*:* Ensuring that all living donors remain financially neutral must be a national priority. While this innovation project addresses the breadth of factors that serve as barriers to living donation, CMS must increase its work to assist donors and transplant centers beyond its currents efforts if the Agency views living donation as a critical component of this effort. In addition, national efforts to facilitate living donor kidney transplants and paired kidney donation should focus on raising awareness, increasing education, and providing comprehensive guidance throughout the entire process, especially for minorities and social-economic underserved communities.

Domain Weighting: AST appreciates the intent of the IOTA model to focus on domains important to improving access to kidney transplantation, greater use of deceased donor organs, and post-transplant quality of care. However, while IOTA is an incentive model targeting transplant hospitals, it is critical to place the model in the context of the overall life cycle of transplant patients, commencing with the referral phase, then successively evaluation, waitlist and transplant-readiness management, transplant surgery and perioperative care, followed by shorter- and longer-term post-transplant care until the transplant kidney is no longer functional. An appreciation of the transplant life cycle could have significant implications for the success or failure of IOTA.

Patients are engaged with their kidney transplant program to differing extents throughout this life cycle, with care provided by a multidisciplinary transplant team. Transplant nephrologists are central to the longitudinal care of patients throughout the transplant cycle, performing comprehensive evaluations, ongoing assessment of transplant readiness and candidacy, perioperative care including DGF management and ongoing aftercare including immunosuppression management, and the diagnosis and treatment of a myriad of early and long-term transplant-related complication. This care is supported by a multidisciplinary team of nurse coordinators, social workers, pharmacists, dieticians, etc. Unpublished AST survey data indicates that about 25 percent of the pre-and post-transplant care delivered by transplant nephrologists to transplant patients is not reimbursed, not patient-facing, and not E&M-related. Even for patients who transition back to the care of their referring nephrologists, the transplant program (and transplant nephrologist) remains their go-to source for any significant transplant or immunosuppression-related issue, a situation compounded by the fact that referring nephrologists invariably do not have resources within their own practices to manage the most complex patients. Nephrologists are not alone in providing uncompensated care. The full spectrum of transplant clinicians (e.g., surgeons, infectious disease specialists, advanced practice providers, coordinators, etc.) may all provide uncompensated care well into the post-transplant time period. As a result, the costs of chronic transplant after-care are frequently borne by transplant programs, while unreimbursed care continues to be delivered by transplant nephrologists and other transplant clinicians indefinitely.

Data from AST indicates that there are approximately 800 transplant nephrologists in the United States. Accounting for approximately 270,000 existing long-term kidney and/or pancreas recipients, 25,000 to 30,000 new transplants per year, 90,000 kidney and/or pancreas candidates on the waiting list (and likely another 25,000 patients in referral or evaluation), the ratio of approximately 500 patients per nephrologist far exceeds that of their dialysis counterparts, or other non-kidney organ transplant subspecialists. Rates of burnout are high, the transplant nephrology workforce is strained, and transplant nephrology training program slots are increasingly going unfilled. A model that incentivizes more transplants, but that does not consider its impact on the capacity of the transplant nephrology workforce runs the risk of over-burdening the system with the unintended consequence of compromising outcomes and quality. It must be understood that more transplants will also require additional resources provided by the transplant hospital on the post-transplant side of the program to support managing a higher transplant volume. Further, this cost is not reimbursed.

For the reasons outlined in the preceding paragraphs in this section, AST recommends that CMS change the relative weight given to the three domains. Weighting the achievement metric focused on quantity at 60 percent may be excessive while weighing the quality of outcomes at only 20 percent is too little. CMS should consider if equal weighting at 33 percent for each domain might be more reasonable and mitigate the potential biases of using a percent increase in transplants performed metric as discussed earlier.

Health Equity Strategy

System Inequities: Efforts to increase equity in transplantation have resulted in improvements, but AST recognizes that more progress must occur. Health equity is especially important in the context of chronic kidney disease. Continuing inequities are illustrated by transplant rates in Black patients, which remain lower compared to transplant rates in other patient populations, despite the higher prevalence of end stage renal disease among Black patients. Inequities are not unique to transplant surgery. A systematic review found that 223 surgery-related outcomes had demonstrated disparities in areas such as provider access, detection of surgical indication, progression to surgery, and optimal care capacity.[iii] Importantly, inequity extends far beyond surgical care, including challenges in access to nephrology care, transplant referral and evaluation, health literacy, etc. Therefore, efforts to effectively address inequities will require system-level collaboration that extends well beyond the field of transplantation.

Social Drivers of Health*:* CMS states that "the model would provide flexibilities for the selected transplant hospitals to participate in addressing barriers related to social drivers of health—such as food insecurity—and require transplant hospitals to establish health equity plans to identify gaps in access." AST agrees that addressing social drivers of health is essential, but kidney transplant centers alone cannot rectify social ills. Even if it were realistic for transplant centers to solve issues such as food insecurity – and to be sure, it is not as we lack both the resources and expertise to do so – it would be of very inefficient and limited in benefit to solve such issues for such a tiny percentage of the affected patients. CMS should also establish programs to address access to medical care, food insecurity, housing, utilities, and transportation through primary care providers, dialysis centers, and other upstream providers to support achievement of this goal for a much greater impact.

Potential for Increased Disparities*:* AST is concerned that the provision in Section 4, Patient Population and Attribution stating that CMS is not differentiating performance regardless of payer type, has the potential to result in preferential selection of patients of non-government payers. CMS should ensure that no systemic biases are introduced and/or implemented into the field of transplantation because of unintended consequences of the IOTA model or other programs.

Resource Needs and Financial Incentives

Program Costs: As noted under the section entitled Risk Mitigation Measures, the proposed financial incentives for the IOTA model would likely result in only minimal

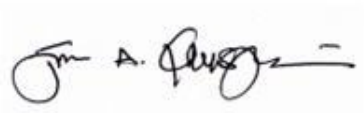
increases in payments to IOTA collaborators. Of note, the IOTA model does not provide an estimate of the costs for transplant centers to implement the program. AST requests that CMS make available an estimate of these costs to inform stakeholder efforts as soon as possible and before this policy is adopted. AST is concerned that the costs of implementation would offset any additional reimbursement that programs would gain, even under the highest levels of performance. As such, the proposed incentives under IOTA are insufficient to drive meaningful change.

Minimal Incentives in the Context of Significant Change and Uncertainty: In addition, IOTA's minimal incentives are being proposed at a time when prior, ongoing, and proposed changes to the transplant ecosystem are already taxing transplant centers and physicians. Efforts to make more organs available have dramatically increased costs at OPOs, where standard acquisition charges to transplant centers have grown at a rate far in excess of inflation. Changes in organ allocation have significantly increased the logistical costs of transplantation, especially transportation. As noted earlier in these comments, CMS has twice initiated proposed changes to reimbursement of organ acquisition costs that would remove more than $400 million per year from transplant hospitals.

These financial impacts, with the workforce and facility limitations noted above, make this a proposal with far too little assessment of the burden on transplant centers and physicians. It also comes at a time of much uncertainty in the transplant ecosystem, with OPTN modernization simultaneously creating change. Put simply, it is not evident that there are enough financial, facility, logistic, and human resources to implement such a proposal. While we welcome the intent of this proposal, we believe this is not the right time for such a program and we believe there has not been enough study of what it will take to be successful. We urge delay in adopting this proposal until the impact of other changes underway in the transplant ecosystem are known. Lastly, AST urges CMS to study the impact of any changes on transplant centers and physicians prior to moving forward.

Thank you in advance for your consideration of AST's feedback. Please do not hesitate to contact me directly if you have questions or require any additional information. In addition, Bill Applegate, AST Director of Government Relations, may be reached at bapplegate@polsinelli.com.

Sincerely,



Jon Kobashigawa, MD
President
American Society of Transplantation

[i] Forcino RC, etc. Do collaboRATE Scores Reflect Differences in Perceived Shared Decision-Making Across Diverse Patient Populations? Evidence From a Large-Scale Patient Experience Survey in the United States. *Journal of Patient Experience.* Available at: https://journals.sagepub.com/doi/full/10.1177/2374373519891039.

[ii] Grillis et al (Milliman Report). Kidney transplantation admission in the Medicare fee for service population, May 2024). Available at: https://www.milliman.com/-/media/milliman/pdfs/2024-articles/5-14-24_milliman-kidney-transplant-lds-report.ashx

[iii] De Jager E, et al. Disparities in Surgical Access: A Systematic Literature Review, Conceptual Model, and Evidence Map. Available at https://pubmed.ncbi.nlm.nih.gov/30803548/.