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July 12, 2024

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5535-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Administrator Brooks-LaSure:

***RE: Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5535-P)***

The Association of American Medical Colleges (AAMC or the association) welcomes this opportunity to comment on the proposed rule entitled “Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model,” 89 *Fed. Reg.* 43518 (May 17, 2024), issued by the Centers for Medicare & Medicaid Services (CMS or the agency).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

The following summary reflects the AAMC’s comments on the proposed IOTA Model:

- ***Model Design.*** Delay the start of the IOTA Model due to the active Organ Procurement and Transplantation Network requests for proposals to reduce potential errors to attribution. In addition, organ procurement organizations must share accountability under this model as they lead the organ donation process.
- ***Quality Domain.*** Include additional measures to fully assess quality performance such as the Hemoglobin A1c poor control (>9%) measure and the Advance Care Plan measure.
- ***Achievement Domain.*** Use a five-year fixed historical period for the baseline calculation to reflect a participant’s past performance more accurately. In addition, shift emphasis from

increasing volume to improving quality by reducing the achievement domain points and increasing the quality domain points.

- **Payment Methodology.** Use the difference between the number of transplants completed and the target as the multiplier in the payment formula to reflect a participant's performance and the population being served.
- **Health Equity.** Include rural patients in the health equity risk adjustment methodology for the achievement domain given the limited access to transplant services in rural areas.
- **Patient Engagement Incentives.** Implement a waiver to expand the use of Medical Nutrition Therapy services to increase the number of patients who meet transplant criteria and can, subsequently, receive a transplant.

## **AAMC COMMENTS IN FULL**

### **MODEL DESIGN**

CMS proposes a mandatory model for improving the quality of care received by individuals requiring kidney transplantation, reducing inequitable outcomes, and improving the efficiency of the transplant process.

***CMS should delay the start of IOTA due to the active Organ Procurement and Transplantation Network requests for proposals.***

The current proposal for IOTA includes a start date of January 1, 2025. With the Organ Procurement and Transplantation Network (OPTN) contract currently set to end in December 2024, there is a lack of clarity around the administration of the OPTN. As HHS evaluates proposals and determines a way forward, CMS should delay the start of IOTA until the vendors are set and can confirm the availability of timely attribution. The possibility of new contractors and multiple vendors also presents a significant risk for errors to attribution which would inhibit beneficiary notification and full implementation of the program.

***CMS should insure accurate, complete attribution no later than one month prior to the start of the program.***

Patient attribution lists are critical to performance in the model. CMS has currently proposed a very short window of 15 days prior to the start of the model for providing these lists. IOTA participants need more time to prepare for the start of the model and ensure that they can accurately gather and report on quality metrics in the program.

***Organ Procurement Organizations must share accountability under IOTA.***

Between 2010 and 2020, more than 1,100 complaints were filed by patients and families, staff, and transplant centers.<sup>1</sup> These reports have included inadequate testing of organs and inefficient delivery of organs, among other significant issues resulting in significant numbers of wasted organs. Nearly a third of donated kidneys are not used.<sup>2</sup> In order to maximize the number of transplants and ensure their quality,

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<sup>1</sup> Wyden, R. [Wyden Statement at Finance Committee Hearing on the Urgent Need to Address Failures in the Organ Transplant System](#), The United States Senate Committee on Finance. (August 2022)

<sup>2</sup> Lentine, K.L., Smith, J.M., Lyden, G.R., et al. OPTN/SRTR 2022 Annual Data Report: Kidney. *American Journal of Transplantation* (2024). Available at: <https://doi.org/10.1016/j.ajt.2024.01.012>

these organ procurement organizations must be held accountable for the quality and timeliness of the organs they provide.

## **QUALITY DOMAIN**

CMS proposes a quality domain which assesses an IOTA participant's performance based on a select group of metrics. These metrics include the Post-transplant Composite Graft Survival Rate Measure and a quality measure set comprised of the CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, and the Three-Item Care Transition Measure (CTM-3). The quality measure set will initially be pay-for-reporting and will transition to a pay-for-performance approach. The AAMC supports both the weight of the kidney-specific portion of the quality domain and the pay-for-reporting structure included in the proposed rule. The quality domain should, however, receive a higher amount of weight in the overall performance assessment structure.

### ***Include Additional Measures to Fully Assess Quality Performance in IOTA.***

To enhance the proposed metrics, CMS should add the Hemoglobin A1c poor control (>9%) (CBE #0559) and Advance Care Plan (CBE #0326) measures to the quality domain to align with the Universal Measures. These measures also align with the other measures in the program and a high standard of care for transplant patients. Specifically, the Advance Care Plan would function alongside the CollaboRATE score to create a complete patient-informed choice.<sup>3</sup>

In addition, CMS should enhance the kidney-specific portion of the quality domain by including the one-year patient and graft survival rate used by private payers as well as the OPTN's Membership and Performance Standards Committee to evaluate performance. It is both a familiar metric and one with an existing benchmark CMS can use to evaluate the IOTA Model against national performance.

### ***Replace the Retired Care Transition (CTM-3) Measure with the proposed "Care Coordination" Sub-Measure.***

To align with the updates to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, CMS should replace the retired CTM-3 measure with the proposed "Care Coordination" Sub-Measure.

### ***Use Patient-Reported Outcomes Measurement Information System (PROMIS) as a Health-related Quality of Life Measure.***

In the proposed rule, CMS requested input on potential Health-related Quality of Life metrics to use in IOTA. AAMC members report current utilization of PROMIS as an effective tool to evaluate Health-related Quality of Life in their patient populations. It is a well-validated measure that aligns well with other quality measurement programs.

## **ACHIEVEMENT DOMAIN**

CMS proposes an achievement domain that assesses an IOTA participant's performance based on the number of transplants performed relative to a target. The transplant target will be based on an IOTA participant's performance over a three-year historical period and a national growth rate. The baseline

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<sup>3</sup> Rosca, A., Karzig-Roduner, I., Kasper, J., Rogger, N., Drewniak, D., Krones, T. Shared decision making and advance care planning: a systematic literature review and novel decision-making model. *BMC Medical Ethics*. (2023). Available at: <https://doi.org/10.1186/s12910-023-00944-7>

performance will be calculated using the highest number of living donor transplants performed during any of the three years and the highest number of deceased donor transplants performed during any of the three years. This baseline and the national growth rate will be trended forward for each performance year.

***Use a five-year fixed historical period for the baseline calculation.***

A kidney transplant hospital's annual volume is often limited to factors beyond their control (e.g., limited organ availability and donor-candidate matching) and may vary year to year. An average of transplant volumes over a 5-year period would more accurately reflect a participant's past performance.

While the model performance years would not factor into a participant's transplant target calculation until the third performance year, this proposed formula penalizes participants for its earlier success by making it more difficult to exceed the target in the future. Using a fixed baseline would ensure participants are able to realistically meet their targets and are not penalized for their success in increasing transplant volumes.

**In addition, CMS should provide each participant with their transplant target three months or at least one month prior to the start of a performance year rather than by the first day of a performance year.** Knowing the transplant target ahead of time will allow participants to prepare for the model.

***Consider adjusting the target thresholds in the achievement domain to be achievable.***

Transplant hospitals are acutely aware of the need to increase access to kidney transplants. However, as noted earlier, external factors influence the number of transplants a hospital can perform even if they have the capacity to do more. The AAMC believes the achievement target thresholds as outlined in "Table 3: PROPOSED ASSESSMENT OF ACHIEVEMENT DOMAIN" in the proposed rule will limit a participant's opportunity to earn more than 30 points in this domain. For example, if a hypothetical transplant hospital had a historical baseline of 250 transplants and there is a 6% growth rate, their target would be 265 transplants. This hospital would have to increase their volume by 130 transplants in one year (150% of the target = 398 transplants) to earn the full 60 points. The achievement target will be increasingly more difficult to meet with each performance year and will potentially offset any intended model effects on transplant hospital behavior. CMS should consider target thresholds that participants can reasonably meet.

***Reduce the number of points available in the achievement domain and increase the number of points available in the quality domain.***

In the proposed rule, CMS notes that one aim of this model is to support greater care coordination, increase care delivery capabilities, and encourage investments in value-based care by tying payments to value. However, the quality domain is allocated only 20 out of 100 points while the achievement domain has the highest number of points with 60 out of 100 points. The proposed scoring system incentivizes increasing volume over improving quality. AAMC members have noted that allocation changes in kidney transplantation have an impact on the quality of the kidney offered. This model may encourage transplant hospitals to use kidneys of lesser quality to meet target thresholds and earn more points, which can lead to worse patient outcomes. Research has shown that kidneys with a higher kidney donor profile index

(KDPI) have an increased risk of graft failure in the first years after transplant.<sup>4</sup> AAMC members raise concerns that higher volumes of marginal kidneys will likely lead to negative outcomes which may trigger a performance review by the OPTN Membership and Professional Standards Committee (MPSC) and result in a hospital's exclusion from some payer networks. Commercial insurers use the one-year patient survival measure to determine which transplant hospitals are allowed in their networks. By reducing the points earned in the achievement domain and increasing the number earned in the quality domain, less emphasis will be placed on increasing volume and more focus will be placed on improving quality.

## **EFFICIENCY DOMAIN**

CMS proposes an efficiency domain that assesses an IOTA participant's performance based on a ratio of the number of organ offer acceptances versus the number of expected organ offer acceptances. CMS proposes using the OPTN measure specifications and current SRTR methodology but with a higher threshold to calculate the organ offer acceptance rate ratio.

***Consider the use of organ offer acceptance filters and the impact it will have on the organ offer acceptance rate ratio.***

While the AAMC understands the importance of reducing the number of unused organs that are transplanted, AAMC members raised concerns that organ offer filters (e.g., medical history, social history, and death details of the donor kidney) may be used to improve the appearance of a participant's organ offer acceptance rate ratio. Transplant hospitals can use filters to lower the number of potential organ offers by eliminating marginal kidneys from consideration.<sup>5</sup> These hospitals will benefit from having a better offer acceptance rate ratio, but hospitals who depend on accepting and transplanting marginal kidneys to increase their volume will have a worse offer acceptance rate ratio. CMS should share details on how this acceptance rate ratio will be audited and ensure participants will not be rewarded for using filters to improve offer acceptance metrics.

The AAMC also has concerns on the additional administrative burden placed on participants to keep track of potential offers against offer acceptances.

## **PAYMENT METHODOLOGY**

***Use the difference between the number of transplants completed and the target as the multiplier, versus number of Medicare transplants.***

CMS has proposed to apply an upside risk and downside risk payment structure based on the final performance scored earned from the three performance assessment domains. For the first performance year, there will be only upside risk and a neutral zone, and downside risk would apply starting in performance year two. The AAMC supports CMS' proposal to implement a two-sided risk payment

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<sup>4</sup> Bachmann, Q., Haberfellner, F., Büttner-Herold, M., et al. The Kidney Donor Profile Index (KDPI) Correlates With Histopathologic Findings in Post-reperfusion Baseline Biopsies and Predicts Kidney Transplant Outcome. *Frontiers in Medicine* (2022). Available at: <https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2022.875206/full>

<sup>5</sup> King, K.L., Husain, S.A., Cohen, D.J., Schold, J.D., Mohan, S. The role of bypass filters in deceased donor kidney allocation in the United States. *American Journal of Transplantation* (2022). Available at: [https://www.amjtransplant.org/article/S1600-6135\(22\)08241-7/fulltext](https://www.amjtransplant.org/article/S1600-6135(22)08241-7/fulltext)

methodology. However, the downside risk payment formula penalizes participants who perform more transplants, but who do not meet the scoring threshold for upside risk. For example, if a hypothetical participant qualified for downside risk with a score of 35 and completed 20 transplants, they would owe \$5,000, but if they completed 10 transplants instead, they would only owe \$2,500. In addition, as the payment multiplier does not include patients with Medicare Advantage (MA), the upside risk and downside risk payments will shrink as the MA population continues to grow. Instead of using the number of Medicare transplants in the payment calculation, CMS should take the difference between the number of transplants completed and the target as the multiplier.

## **FINANCIAL ARRANGEMENTS**

***CMS should remove the 50% cap on gainsharing.***

CMS proposes to allow gainsharing of Medicare savings and costs between IOTA participants and other entities. Safe harbor regulations will apply, and CMS proposes an overall cap of 50% on gainsharing payments. **The AAMC supports the options for gainsharing as it encourages collaboration between specialists and post-acute care providers, however we recommend that CMS remove the 50% cap on gainsharing.** Removing the gainsharing cap would reduce the administrative burden for providers, strengthen integration between specialists and post-acute care providers, and maintain consistency with other CMS models.

## **MODEL OVERLAP**

CMS proposes to allow overlaps between the IOTA Model and other Innovation Center models and CMS programs. **The AAMC supports CMS' decision to allow overlap between IOTA and other models as the IOTA Model provides performance-based payments separate from FFS payments.**

## **DATA SHARING**

CMS states that the IOTA Model participants will receive, upon request, claims-level data for the beneficiaries attributed to IOTA participants, as well as aggregate data to assist with quality improvement and model activities. **The AAMC supports CMS' decision to include this level of data in the IOTA Model, however, we encourage CMS to expand the data offering by providing cost and utilization claims-level data to assist IOTA participants in conducting model activities.**

CMS has proposed to include a subsection of claims data, upon request, to IOTA participants. However, the level of data proposed does not currently meet the needs of IOTA participants. CMS should include cost and utilization claims-level data to assist providers in serving transplant patients. Given that CMS is encouraging the use of marginalized organs, it is important to also track the costs and service utilization associated with transplants using a marginalized kidney. Ultimately, using these organs could lead to worsening outcomes for transplant patients, and, therefore, CMS should provide and track cost and utilization data to determine higher readmissions, emergency department use, and other service utilization and costs that indicate poor outcomes outside of graft failure.<sup>6</sup>

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<sup>6</sup> Journal of the American Society of Nephrology, "Survival in Recipients of Marginal Cadaveric Donor Kidneys Compared with Other Recipients and Wait-Listed Transplant Candidates." (2001). Available at: [https://journals.lww.com/JASN/fulltext/2001/03000/Survival\\_in\\_Recipients\\_of\\_Marginal\\_Cadaveric\\_Donor.21.aspx](https://journals.lww.com/JASN/fulltext/2001/03000/Survival_in_Recipients_of_Marginal_Cadaveric_Donor.21.aspx)

***Provide monthly claims data for IOTA participants' attributed beneficiaries and ensure initial data is delivered in a timely manner.***

CMS has proposed that IOTA participants can request claims data, through the data attestation form. CMS should provide this data monthly to ensure timely opportunity to influence performance. Model participants often comment that one of the most difficult issues with value-based care models is the actionability of the data provided, given the time lags. CMS should, therefore, ensure that they provide data as quickly and as frequently as possible. Additionally, CMS has stated that claims data will be provided no earlier than 30 days after the start of a performance year. CMS should strive to provide this data as early as possible to ensure providers have the necessary data to monitor performance in the model and address patients' needs. CMS should provide this data with the start of each performance year.

## **HEALTH EQUITY**

CMS has integrated health equity initiatives into all newly announced value-based care models, working to decrease disparities in health, care, and access. The AAMC greatly supports CMS' work to strengthen health equity in value-based care but recommends changes to the achievement domain risk adjustment to ensure CMS is appropriately capturing patients' unique characteristics.

***Include rural patients in the health equity risk adjustment methodology for the achievement domain.***

CMS is seeking comments on the inclusion of rural patients in the health equity risk adjustment for the achievement domain. The AAMC believes that CMS should include rural patients in the adjustment, given the limited access to transplant services in rural areas. Rural patients are less likely to be added to the transplant waitlist, as well as be referred for transplant by a dialysis provider.<sup>7</sup> The rural population experiences disproportionate barriers to accessing transplant services. Therefore, CMS should incentivize IOTA participants to care for rural patients through the increased adjustment for low-income patients. If CMS is concerned about labeling all rural patients as low-income, CMS could change the name of the risk adjustment to appropriately capture the vulnerable populations included in the adjustment.

## **TRANSPARENCY**

CMS plans to include several specific requirements around transparency that will improve a patient's knowledge and education on transplant services and the organ offer process. The AAMC supports CMS' decision to implement initiatives that increase patient-centered care; however, we maintain concerns with regards to notifying patients about organs offers not selected.

***Require IOTA participants to discuss why organ offers may not be accepted during initial attribution but do not require monthly discussions for each month an organ was offered.***

Sending monthly notifications as well as responding to patient questions from these notifications will require extensive resources. This is counterproductive to the model aim of reducing costs. CMS should, therefore, only require IOTA participants to discuss with patients, during initial attribution, the specific conditions that would lead to an organ refusal, rather than sharing each time an organ is not accepted.

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<sup>7</sup> International Journal of Health Equity, "A scoping review of inequities in access to organ transplant in the United States." (2022). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8841123/>.

## **BENEFICIARY NOTIFICATIONS**

CMS, as with all models, requires IOTA participants to notify attributed beneficiaries of the transplant hospital's participation in the model. The AAMC supports patient choice and the need to inform patients on providers' participation in the model.

### ***Provide beneficiary notifications in multiple languages.***

The AAMC supports CMS' decision to enhance patient choice by notifying patients of a transplant hospital's participation in IOTA. CMS should offer the beneficiary notification in multiple languages to meet the needs of beneficiaries. The United States maintains regional variations regarding common languages spoken, therefore, CMS should offer various languages tailored to specific patient populations.

## **PATIENT ENGAGEMENT INCENTIVES**

CMS is offering several patient engagement incentives to increase access to transplant services by decreasing barriers to care, such as transportation, communication, costs, and behavioral health issues. The AAMC supports CMS' decision to include these offerings to increase access and recommends the inclusion of a waiver to increase the availability of nutritional services, as well as some alterations to the proposed patient engagement incentives.

### ***Implement a waiver to expand the use of Medical Nutrition Therapy services.***

Diet is an extremely key factor for patients undergoing a kidney transplant. Obesity can increase the rate of surgical complications, as well as the rate of comorbid conditions that could lead to worsening health and post-transplant outcomes.<sup>8</sup> Currently, CMS offers Medical Nutrition Therapy for Medicare patients with a diagnosis of renal disease, providing three hours of therapy in the initial year of service and two hours in subsequent years. CMS should expand the hours covered for these services for IOTA patients to increase the number of patients who meet transplant criteria and can, subsequently, receive a transplant.

### ***Offer additional Part B and D immunosuppressive drug payment supplements for low-income patients.***

CMS considered paying in full for Part B and Part D immunosuppressive drugs, as the cost is often a limiting factor for patients needing a transplant. While the AAMC understands that providing this waiver for all patients would result in model losses for Medicare, CMS should consider offering full cost coverage for those patients included on the low-income list for the achievement domain's health equity risk adjustment. As CMS stated in the proposed rule, socioeconomic status accounted for a third of patients who are Black from being placed on the transplant waitlist. Without additional assistance, disparities will increase. While the cost-sharing incentive is a good step to increasing access, CMS should consider covering the full cost of these drugs for patients who qualify as low-income, based on the definition outlined in the proposed rule, who are not currently receiving cost-sharing subsidies.

## **MONITORING**

CMS proposes to include several mechanisms for monitoring model activities. The AAMC agrees with these policies. However, with regards to site visits, **CMS should provide greater notice than 15 days prior to a site visit.** Given the high burden on providers, who may need to cancel necessary medical

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<sup>8</sup> Nephrology Dialysis Transportation, "Management of obesity in kidney transplant candidates and recipients: A clinical practice guideline by the DESCARTES Working Group of ERA." (2022). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8712154/>.



appointments to accommodate the site visit, CMS should provide at a minimum a 30-day notice for a site visit.

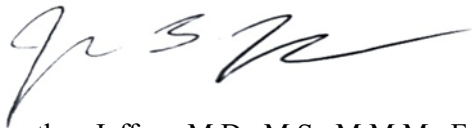
## **LEARNING**

CMS proposes to provide an IOTA-specific learning system, retiring the previous learning system used for the ESRD Treatment Choices Model. **The AAMC supports CMS' decision to implement a specific learning system for IOTA to increase the benefit of participation in learning activities to transplant hospitals.**

## **CONCLUSION**

Thank you for the opportunity to comment on this proposed rule. If you have questions regarding our comments, please feel free to contact my colleagues – Keith Horvath, Sr. Director, Clinical Transformation ([khorvath@aamc.org](mailto:khorvath@aamc.org)) or Michelle Spafford, Manager, Value Based Care ([mspafford@aamc.org](mailto:mspafford@aamc.org)).

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Jaffery', with a long horizontal flourish extending to the right.

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.  
Chief, Health Care Affairs

cc: David Skorton, M.D., AAMC President and Chief Executive Officer