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February 6, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5544-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Oz,

The AAMC¹ welcomes this opportunity to comment on the proposed rule entitled “**Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access IOTA) Model,**” 90 FR 57598 (December 11, 2025), issued by the Centers for Medicare & Medicaid Services (CMS or the agency).

The AAMC is concerned policies proposed would place significant new operational burdens on transplant centers, potentially amplify confusion for patients, and undermine quality scoring with inconsistent risk adjustment models. Additionally, since issuing this proposed rule for the IOTA Model, the agency has issued a separate proposed rulemaking to revise Organ Procurement Organizations (OPOs) Conditions for Coverage.² Altogether, we urge CMS to reconsider updating and revising the IOTA Model or finalize additional performance periods with no downside financial penalties, until there is greater clarity on the interactions with other regulatory requirements impacting the nation’s organ transplantation system to ensure that IOTA requirements do not confuse and frustrate patients and transplant programs. The AAMC’s comments in response to specific proposals follow.

¹ The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 162 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 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 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

² 91 FR 4190 (January 30, 2026).

MODEL REQUIREMENTS

CMS Should Not Risk Confusing Patients and Increasing Burden on Transplant Programs with Proposed Communications with Waitlist Patients

CMS proposes to require IOTA participants to notify Medicare waitlist patients (1) of the number of times an organ is declined on the patient's behalf at least once every six months that the patient is on the IOTA participant's waitlist and (2) when their status changes from active to inactive within ten business days.

The AAMC supports the agency's intent to enhance communication and care coordination. However, the proposed requirements would create an immeasurable operational burden and should not be finalized. Many programs do not currently have the administrative infrastructure or staffing to support communication with potentially larger volumes of active waitlisted candidates. Implementing such requirements would likely necessitate significant new costs and workflow redesign and may lead to confusion rather than clarity for patients about their status, options, and expected outcomes. Without clear guidance on how these communications should occur, what constitutes acceptable documentation, and how regulatory compliance will be measured, these proposed notifications requirements risk overwhelming transplant programs, diverting clinical resources, and potentially delaying transplant care.

Declined Organ Offers

Regarding semiannual notification on the number of organs declined to IOTA waitlist patients beginning in Performance Year (PY) 3 (July 2027), we have significant concerns about the potential administrative burden and the risk of patient confusion or notification fatigue. As proposed, transplant programs will be required to notify all Medicare waitlisted patients every six months who have accrued a minimum of three years of waiting time of the organs that have been declined on their behalf. (p. 57615).

We believe that the topics required for this communication with the patients will be both confusing and overly detailed, likely including information that may not be actionable to the patient. Because of the allocation system, some patients would receive a high volume of declined offers, many never reviewed by the transplant surgeon due to system rule out criteria or OPO declines. Additionally, there are situations in expedited placement or directed donor scenarios for kidneys in which kidneys are allocated at higher sequence numbers and the OPO enters a decline code for all candidates listed above the designated recipient; in these cases, the transplant center is likely unaware of the "offer." Finally, many of the final acceptance/denial criteria are based on individualized clinical judgment and require physician assessment, which cannot be fully or accurately captured and defined well for patient review.

We also have significant concerns with the requirement that a nephrologist or nephrology professional must be available to assist the patient with this review, as they are not always involved in the organ offer review process, and including them in that process will take away already limited availability for new patient evaluations, patient follow-up, inpatient care, etc.

Every organ offer received is reviewed at length by the surgical team, and every effort is made to transplant organs that are believed to improve the quality of life for the patient. Discussing with the patient offers that are not suitable has the potential to be confusing, take away valuable resources from direct patient care, and lead to patients questioning or losing trust in their transplant center.

Finally, the agency's projected burden on transplant hospitals for this requirement estimates it will take 15 minutes a year for each waitlisted patient at a cost of \$6,346 per year for 200 waitlisted Medicare patients. (p. 57627) We believe this is a gross underestimate, given the required discussion points, and that CMS erred in basing the cost estimate on that of a nurse practitioner when the requirement includes review by a nephrologist.

Waitlist Status Changes

Specific to patient waitlist status changes, patient inactivation is often temporary and multifactorial, such as those related to insurance authorization or pending test results. Requiring detailed, step-by-step reactivation instructions in these circumstances may create an unnecessary administrative burden and contribute to patient anxiety or confusion.

Ensure Publication and Review of Selection Criteria Does Not Reduce Patient Engagement and Aligns with Other Requirements

CMS proposes two requirements for IOTA participants to publish organ selection criteria: (1) living donor and (2) annual review of selection criteria. The AAMC recommends removing the requirement to publish living donor selection criteria. Selection is patient specific and so nuanced, that posting publicly would cause confusion and potentially deter donor inquiry because of assumptions of ineligibility. The impact would likely decrease donor screenings and potentially decrease living donor transplant volumes, ultimately undermining the model's goal of increasing transplant volumes overall. Regarding the review of the program's selection criteria, the AAMC recommends that CMS modify the requirement for review of recipient selection criteria from an annual model PY basis and instead align with three-year accreditation cycles for reviewing hospital policies.

Amend Electronic Patient Notifications Rules to Refer to Patients Opting In

CMS proposes to allow electronic patient notifications where patients "opt out" of receiving paper notifications by revising requirements under §512.450. (p. 57634) The AAMC strongly supports electronic notifications but urges CMS to reconsider the framing of the policy to instead refer to patients who "opt in" to receive notifications electronically. Standard electronic health records systems code functionality for electronic notifications around opt-ins and not opt-outs.

Provide Greater Clarity on Agency Monitoring Efforts

CMS includes a list of monitoring activities it will undertake to ensure IOTA participant compliance with model requirements. (p. 57622) The AAMC requests clarification on the overall

monitoring structure, including the types of monitoring to be conducted, monitoring frequency, and how compliance will be assessed in relation to existing regulatory and reporting requirements.

PERFORMANCE ASSESSMENT - QUALITY DOMAIN

Align Measure Risk Adjustment with Scientific Registry of Transplant Recipients (SRTR) Methodologies

CMS proposes to begin risk-adjusting the composite graft survival rate metric to account for multiple transplant recipient and donor characteristics. (p. 57605) Notably, the agency declines to implement the SRTR risk-adjustment methodology in part due to concerns with complexity and need for additional educational resources and sophistication to interpret performance. (p. 57606) The AAMC supports the addition of risk adjustment to improve the accuracy of performance measurement, but we urge CMS to reconsider risk adjustment based on the SRTR methodology.

We ask CMS to further elaborate on the Agency's proposed variables and how they are an improvement to the existing SRTR methodology. The proposed recipient risk-adjustment variables include age, sex, kidney function (eGFR/creatinine), diabetes, hypertension with or without cardiovascular disease, human leukocyte antigen (HLA) mismatch, and Panel Reactive Antibody (PRA) levels.³ Specifically, kidney transplant candidates must be on dialysis or have an eGFR or cystatin C <20 to accrue waitlist time; creatinine values in dialysis patients fluctuate post-dialysis and do not accurately reflect kidney function for risk adjustment. Established models commonly include factors such as recipient peripheral vascular disease, ischemic cardiac disease, and serum albumin, which are not addressed in the agency's proposed methodology. The AAMC also recommends CMS consider including the recipient's accessibility to the transplant center to recognize access and transport issues post-transplant, particularly in rural areas. The proposed donor characteristics similarly warrant clarification, particularly the inclusion of donor PRA, as PRA does not apply to organ donors.

Additionally, the AAMC seeks clarification on how donor and recipient data will be obtained and validated for purposes of the proposed risk adjustment methodology. Unlike SRTR processes, which allow programs an opportunity to review and correct data before public reporting, we are concerned that incomplete data, particularly donor factors from OPOs, could compromise the accuracy of risk adjustment. CMS should allow transplant programs to review, complete, or correct donor and recipient data used for this model if adopted.

Finally, IOTA participants would be subject to different performance standards if CMS does not align with SRTR methods, as SRTR standings are often used by other payers when establishing Center of Excellence (COE) status. IOTA participants would likely assess the financial and

³ The proposed rule represents PRA as "plasma renin activity" for purposes of risk adjustment variables, but we believe CMS intended to reflect Panel Reactive Antibody.

referral impacts of these different standards and likely follow SRTR outcome measures to best meet the model's goals of completing the most transplants.

Exclude Multi-Organ Transplants from Pay-for-Performance Measurement

CMS proposes to exclude multi-organ transplants (except kidney/pancreas transplants) from the composite graft survival rate used to assess performance in the model. (p. 57608) The AAMC appreciates the agency's recognition of the increased complexity of clinical outcomes associated with multi-organ transplant procedures.

Consider Alternative Approaches to Awarding Points for Quality Performance

CMS proposes an alternate scoring methodology to translate quality performance based on national quintiles of performance to calculate points IOTA participants may earn for quality towards their total score to determine payment implications under the model. Under this new policy, any transplant program below the 20th percentile nationally would not earn any points in the Quality Domain. (p. 57610) **The AAMC does not support this policy and instead recommends that CMS eliminate a relative ranking system and instead consider an approach utilizing set award points to meeting an acceptable level of performance and performance above that level.** We are concerned that a quintile-based structure, where the bottom quintile cannot achieve any points, might inadvertently discourage transplant programs from accepting medically complex organs, which are highly incentivized through the more heavily weighed domains (Achievement [number of transplant procedures] and Efficiency [organ acceptance rate]).

Future Pre-transplantation Access Process Measures Must Only Measure That Which is in Control of the Transplant Program

CMS seeks feedback on future use of pre-transplantation access process measures in the quality domain. (p. 57622) The AAMC is supportive of measures that could help support access improvements, but use of such measures in a performance program requires fine tailoring to ensure measured entities, in this case transplant programs, are held accountable only for that which they can control. Patient flow for many transplant programs is through the referral and listing processes and is dependent on variables the program cannot change. Common delays are related to cardiac clearance post-intervention, access to patients' local testing, and dental clearances not within the control of the transplant program.

PAYMENT INCENTIVES

Provide More Information on the Potential Future Inclusion of Medicare Advantage (MA) Patients Within the Definition of Medicare Kidney Transplants

CMS solicits feedback regarding the potential future inclusion of Medicare patients enrolled in MA plans given MA enrollment trends and potential impacts on model incentives. (p. 57611) The AAMC asks CMS to provide more information for IOTA participants to better understand how the inclusion of MA patients in the model would impact their chances of successfully meeting the model's goal of increasing patients' access to kidney transplants. We are concerned that the impacts of MA inclusion will in part be a function of the degree to which MA plans differentially apply utilization management or other administrative processes to kidney transplant services relative to fee-for-service (FFS) Medicare. To the extent that plans are more restrictive in covering these services relative to FFS, transplant centers in markets with high (or growing) MA penetration would be disadvantaged under the model. CMS could provide, for example, statistics on the differential rate of kidney transplants per capita covered by MA and FFS Medicare over a period (e.g., 2019-2024) in the model's selected Donation Service Areas and calculate model performance under the current FFS basis during that period in comparison to performance with MA patients included.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic medicine community. If you have questions regarding our comments, please feel free to contact Phoebe Ramsey (pramsey@aamc.org).

Sincerely,



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Chief Health Care Officer

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