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February 9, 2026

Administrator Mehmet Oz, M.D.
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-5544-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-5544-P – Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model, published at Vol. 90, No. 236 Federal Register 57598-57634 on December 11, 2025.

Submitted electronically via http://www.regulations.gov

Dear Administrator Oz,

UnityPoint Health appreciates this opportunity to provide comments on the proposed rule related to the Increasing Organ Transplant Access (IOTA) Model. Iowa Methodist Medical Center, a senior affiliate of UnityPoint Health, is located in Des Moines, Iowa, has performed kidney-only transplants for more than 30 years, and is an IOTA Model participant. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 29,000 employees and our relationships with more than 390+ physician clinics, 36 hospitals in urban and rural communities, and 12 home care areas of service across our 8 regions, UnityPoint Health provides care throughout Iowa, central Illinois, southeastern South Dakota, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8 million patient visits.

UnityPoint Health and Iowa Methodist Kidney Transplant Center (IAIM) appreciates the time and effort of CMS in revising the IOTA model. We respectfully offer the following input.

GENERAL COMMENTS

The IOTA Model is a 6-year mandatory alternative payment model tested by the CMS Innovation Center that began on July 1, 2025, and will end on June 30, 2031. This proposed rule would update IOTA Model provisions in response to improvement opportunities and to better align with new administration priorities. The IOTA Model is aimed at kidney transplant hospitals with the goal of increasing the number of kidney transplants, improving quality, and improving patient experience during the transplant process.

Comment: The vision of UnityPoint Health and Iowa Methodist Kidney Transplant Center (IAIM) is "best outcome, every patient, every time." **In 30 years, IAIM performed 1430 kidney transplants.** Our small rural Transplant Center has historically had a small waitlist with a higher risk population, including elderly

patients and patients with elevated BMI and histories of smoking and vascular/cardiovascular disease. Nearly all our transplant recipients reside within 250 miles of our center. In the evolving regulatory landscape of the past five years, we are proud that IAIM has not been flagged for graft or patient survival metrics, has held a steady transplant rate, and has had many successful UNOS and CMS site surveys with no citations.

It is firmly established that kidney transplants can be the best option for ESRD patients offering long-term survival, no dialysis, heightened quality of life, and a lower cost to the health care system. It is also clear that ongoing federal updates to increase accountability in organ recovery and transplantation are necessary and, in many instances, these changes are showing overall improvement. **IAIM is committed to and supports the CMS goals of improving access and reducing disparities in kidney transplant, as well as holding Organ Procurement Organizations (OPOs) and Transplant Centers accountable for established best practices**.

Despite the promise of reform, the IOTA Model (building upon OPTN Initiative allocation changes) has not increased opportunities for organ access by IAIM patients. The American Hospital Association (AHA) foreshadowed IOTA Model concerns and unintended consequences in its 2024 comment letter[1] to CMS, and **IAIM can attest that IOTA has not improved meaningful access at our center**:

- IOTA has added disruption and uncertainty to our transplant ecosystem, which was already strained due to declining volume from the allocation change. The stress of downside risk puts our Transplant Center and more importantly our patients at risk, despite favorable national comparisons for transplant rate ratio (1.61)[2], removals from waiting list for receipt of donor transplant (46.4%)[3], median length of stay for all transplants (3 days)[4], and waitlist time (2 years, 10 months)[5]. Medicare and Medicaid cover 62% of our patients.[6] Many of our patients are on fixed incomes, are of advancing age (70+ years are 15% of our waiting list and 25% of our deceased donor recipients)[7], and have multiple co-morbidities making then particularly dependent upon IAIM's central location in our state avoiding extensive travel and added expenses to seek care at other Transplant Centers.

[1] https://www.aha.org/lettercomment/2024-07-16-aha-letter-cms-increasing-organ-transplant-access-iota-model
[2] IAIM SRTR Data Report: 07/01/2023 to 06/30/2025 (release date January 6, 2026, and based on data available October 31, 2025).
[3] IAIM SRTR Data Report: 01/01/2023 to 12/31/2023 (release date January 6, 2026, and based on data available October 31, 2025) – IAIM had 39.5% removed due to receipt of deceased donor transplant (22.5% nationally) and 7.2% removed due to receipt of living donor transplant (6.6% nationally).
[4] IAIM SRTR Data Report: 07/01/2024 to 06/30/2025 (release date January 6, 2026, and based on data available October 31, 2025) – Nationally, the median length of stay is 5 days for deceased donors and 3 days for living donors.
[5] TransplandCoach.com Wait Times, based on OPTN data as of December 11, 2025, accessed at https://transplantcoach.com/
[6] IAIM SRTR Data Report: 2024 and 2025 (release date January 6, 2026, and based on data available October 31, 2025).
[7] IAIM SRTR Data Report: 07/01/2024 to 06/30/2025 (release date January 6, 2026, and based on data available October 31, 2025) – Nationally, 70+ years represents 6.7% of the waiting list and 13.4% of deceased donor recipients.

- IOTA's mandatory participation involving downside risk subjects small Transplant Centers like IAIM to unwarranted penalties for outlier cases. In a rural state with low population density and higher risk recipients and donor populations, the quality of offers has steadily declined since 2021. This further reduces overall transplants, overemphasizes any variance, and erodes both the validity and reliability of IOTA Model generalizations or performance conclusions.
- IOTA's emphasis on volume has exacerbated inequities. With performance predominantly measured through the ability and capacity to surpass volume benchmarks, this fails to account for the "quality" of offers. Simply put, the bulk of viable offers are not extended to some Transplant Centers – for IAIM, we cannot control our short waitlists and riskier recipient profiles. While IAIM has historically and continues to accept offers from older donors, IAIM will not accept risky offers that jeopardize patient safety.

As structured, IOTA's achievement domain and OPTN Initiative allocation changes provide no opportunity for IAIM to "win" under the model, despite our use of best practices and corresponding wins for our patients. In addition to reimbursement implications, CMS will post results from which patients, providers, and the public may reasonably infer (despite factual inaccuracy) that performance losses reflect subpar transplant programs. While there is always room for improvement, the starting line for IOTA Model Participants is not the same – IAIM's waitlist patients and geography limits organ offers. **We urge CMS to reevaluate the distribution of Transplant Centers across performance measures for best practices and trends (positive and negative). Specifically, the impact of geography, waitlist characteristics, and offer opportunities should be targeted.** We are concerned that a push to match marginal kidney offers may put patients at risk (or compromise the patient experience) to achieve metrics set on a national level to avoid a monetary penalty.

QUALITY ASSESSMENT

CMS proposes to include a risk-adjustment methodology in the composite graft survival rate calculation to account for multiple transplant recipient and donor characteristics. The methodology excludes multi-organ transplants except for kidney/pancreas transplants. Measure scoring is revised to reflect a more even distribution in relation to a national ranking of all eligible kidney transplant hospitals. CMS seeks input on the methodology, scoring, and alternatives considered.

Comment: IAIM generally supports risk-adjustment methodology to differentiate expected patient outcomes. CMS limits IOTA proposed risk-adjustment methodology to calculating composite graft survival rate, as risk-adjustment is already incorporated into the efficiency domain. This methodology for composite graft survival rate:

- **Excludes organ characteristics**. The main focus should be on how Transplant Centers pair marginal kidney offers with higher-risk populations. What is crucial but missing from this equation is the organ quality. In the first six-months of the IOTA Model, five of our top six reasons for organ refusal (78.5%) represent organ characteristics – biopsy results unacceptable; organ preservation: unacceptable method or findings; actual or projected cold ischemic time too long; unacceptable organ specific test results; and organ anatomical damage or defect. Donor medical history was the fourth top reason (11.3%) with all other reasons equaling 10.2%. **CMS should consider including a risk adjustment for graft survival for organs that were refused by other Transplant Centers for**

"quality" reasons, outside of patient choice and recipient/donor characteristics.

- **Is misaligned with current standards.** The proposed recipient and donor characteristics for risk adjustment do not align with the UNOS Kidney Donor Profile Index (KDPI) or Estimated Post-Transplant Survival (EPTS) scoring systems and the risk adjustment variables differ from the Scientific Registry of Transplant Recipients (SRTR) platform. **We recommend that CMS consider using these existing structures for consistency and to reduce administrative burden**.
    - **Specific risk factors:** We are concerned that some of the characteristics are not differentiators – for instance, recipient kidney function dialysis wait time should be included if the patient is on dialysis instead of eGFR/creatinine; and panel reactive antibody (PRA) should just be removed altogether. Additionally, characteristics that are differentiators are omitted – for instance, BMI, race, and history of smoking or drug use are important. For IAIM, only 29% of our state's residents are within normal weight range, which is reflected in our average 30.4 BMI for waitlist patients and, for patients with a BMI >40, IAIM considers this a relative contraindication whereas many Transplant Centers consider this to be an absolute contraindication. IAIM is more aggressive than most Transplant Centers in assisting patients with a BMI risk factor and we encourage CMS to factor BMI into its risk assessment.
    - **Impact on SRTR reports:** With differing risk factors, IOTA and SRTR results will not necessarily align, which is confusing to patients, providers, and the public.
- **Poses data collection challenges.** We agree with CMS that "hypertension and cardiovascular disease represent major outcome determinants present at transplantation that are largely beyond transplant hospitals' short-term control," but cardiovascular conditions are not documented in the required reports (e.g., TRR, STAR file). **In current state, it is unclear how CMS would validate this data**. If reports are revised to include, this may involve labor-intensive manual data extraction or costly upgrades to IT infrastructure.
- **Lacks weighting specificity.** CMS is to apply a risk score, but how recipient and donor characteristics are weighted is silent. Are all characteristics to be equally weighted or should weights vary? **The lack of transparency in risk adjustment calculations makes it difficult for Transplant Centers to understand its true impact**.
- **Fails to provide a preview period:** We urge CMS to embed a review period with correction mechanism for any Center-specific information prior to being publicly posted.

Aside from composite graft survival rate, we request that CMS consider monitoring Delayed Graft Function (DGF) for trends and include a patient experience measure.

MEDICARE ADVANTAGE (MA) PARTICIPATION

MA beneficiaries are currently excluded from the IOTA model. CMS solicits input on whether to include MA beneficiaries within the IOTA model as well as other considerations should CMS proceed with such an approach.

Comment: IAIM recommends that CMS not include additional payers while this model is still under

construction.

PERFORMANCE-BASED PAYMENT MODEL

CMS clarifies the final performance score range, specifies timing and implications of downside risk payments, and updates the extreme and uncontrollable circumstances policy.

Comment: IAIM requests that CMS delay downside risk payments for at least one additional year. With significant changes proposed to the IOTA Model, participating Transplant Centers should be given a full performance year to understand and operationalize these new requirements. As a mandatory model, downside risk was not negotiated and participating Transplant Centers with a history of clean audits, in good standing with CMS and UNOS standards, and with short average lengths of stay, should be given time and latitude to meet performance standards.

During the one-year delay, IAIM requests that CMS revisit IOTA Model performance scoring methodology and how the IOTA Model overlaps with the OPTN Modernization Initiative. Combined, these efforts changed allocation practices (degrading) offer quality and then supersized volume increases to 60% of overall performance. For small rural Transplant Centers, the impact is devastating as there are simply insufficient quality organ offers to sustain current volume without growth goals imposed by CMS. It is impossible to increase transplants if suitable organs are not available.

Particularly, **CMS should evaluate holding Transplant Centers financially harmless for poor achievement scores if the pool of offers does not represent "quality" offers/organs and scores on quality and efficiency domains are disproportionately higher than performance scores**. After the OPTN allocation change, organ offers went up significantly across the country as OPOs recovered more organs. With increased access, CMS encouraged all Transplant Centers to increase their organ offer acceptance rate. In the upper Midwest, IAIM is situated in the middle of several major Transplant Centers – Omaha, Chicago, Minneapolis/St. Paul, and Kansas City. The majority of OPO organ offers now go to these major centers since they have longer wait lists and a longer wait time. Predictably those major Transplant Centers started accepting more primary and other offers from the larger donation pool. At IAIM, offers also increased but our offer acceptance rate started to trend downward. Historically our acceptance rate has been very high, but the rate of marginal kidneys in the offer pool exponentially increased. With our shorter waitlist and a higher risk population, it is challenging to convert offers into transplants. From 2020 to 2025, IAIM experienced a 163% increase in the percentage of Delayed Graft Function (DGF).

TRANSPARENCY REQUIREMENTS

CMS revisits transparency requirements related to publication of selection criteria for kidney transplant evaluations and waitlisting; publication of IOTA participant selection criteria; transparency into kidney transplant organ offers; review of acceptance criteria; and change in waitlist status. CMS also proposes to remove the health equity plan requirements.

Comment: IAIM supports requirements that Transplant Centers annually update their websites related to IOTA Model participation, including waitlist evaluation and selection criteria. We also support messaging that patients have a choice and that regular communication of waitlist status is appropriate. Patients are part of our team, and we work hard to build their trust.

We vehemently oppose the detailed messaging proposed for kidney transplant organ offers in PYs 3

through 6. IAIM reviews EVERY AND ALL offers received – thousands in a 6-month period. The minutia proposed to be communicated to waitlist patients every 6 months on each offer and decline is staggering (i.e., §512.442(b)(1)), and we question whether it is meaningful to patient experience. Instead of empowering patients, it is likely that these communications will have the opposite effect - patients will be overwhelmed and confused by the complexity of the information, frustrated by the sheer volume of offers / donors / recipients, scared by a process of not finding a match, discouraged by patient-specific attributes limiting acceptance, angry with providers for declined organs that were ultimately transplanted, and hopeless when there is a lack of realistic avenues to accelerate transplant access. The emotional health of waitlist patients is often fragile, and rehashing each offer decline can be disheartening and even cruel. **We recommend that CMS either (1) change this process to an opt-in at the time of listing or (2) significantly reduce the amount of information required to include waitlist status and the general acceptance criteria.**

REQUEST FOR INFORMATION: PRE-TRANSPLATATION ACCESS PROCESS MEASURE

CMS states that implementation of a pre-transplant outcome or process measure in the IOTA Model would serve multiple strategic objectives: identification and remediation of process inconsistencies, reduction of waitlist mortality through optimization of referral-to-transplantation intervals, and quantification of clinical practice variations across kidney transplant hospitals. CMS seeks public comments accompanied by empirical evidence whenever possible.

Comment: IAIM appreciates that CMS is seeking stakeholder input and urges CMS to carefully weigh the collection burden and associated costs for a new pre-transplantation access process measure. Transplant Centers already track and report many indicators when patients are registered on the waitlist, which reporting continues post-transplant. In the absence of a specific measure proposal, it is difficult to opine on the time and effort as well as software builds required but it is estimated to be significant for Transplant Centers already experiencing reduced reimbursement and more regulatory requirements.

REQUEST FOR INFORMATION: ALLOCATION OUT-OF-SEQUENCE (AOOS)

AOOS remains an issue of concern for CMS and HRSA. As a result, CMS seeks public comments from all stakeholders.

Comment: IAIM believes that AOOS can be appropriate to timely match offers to waitlist patients and avoid organs being discarded. While we acknowledge that this practice has been ripe for unethical behavior by some OPOs and providers, the potential for AOOS to save lives is real. From 2022 through 2024, the rate of kidney discards hovered around 25% until slightly declining in 2025.[8] Timing of organ recovery also impacts transplant access. It is common for deceased donor organs to be recovered in the middle of the night or on weekends to accommodate open Operating Room time, which restricts air flight availability and can increase Cold Ischemic Time. **We agree that CMS guardrails for AOOS are needed, particularly to allow for emergency situations or when travel and time constraints will not support a sequenced allocation**.

Prior to 2021, AOOS had been a literal lifeline for IAIM patients. Our Transplant Center is located in a

[8] *Impact of regulatory pressure on kidney recovery and utilization in the United States,* Transplantation, p S54 (December 2025)

Midwest rural state, and although our waitlist is small, our recipients have higher lifestyle risks (BMI, smoking, and vascular/cardiovascular history). **When viable offers filter to IAIM, organ transport is often a deciding factor and, when air travel is involved, IAIM is at a significant disadvantage.** Our state is one of 14 states whose largest Primary airports are classified by the FAA as either a Small Hub or Nonhub.[9] We have two Small Hubs (one located in our town and the other located two hours away by car). These airports have limited direct flights and generally infrequent flight times serviced by a few commercial airlines. This hampers IAIM's ability to accept organ offers from outside a 250-mile radius, compounding the dearth of viable offers directed to our small waitlist. As a result, IAIM has a significant drop off in "Shared" offer acceptance for longer Cold Ischemic Time (71.9% for 12-21 hours vs. 21.9% for 22-31 hours)[10].

To illustrate when AOOS would be appropriate to match "hard-to-place" organs, a Transplant Center receives an offer from a 70-year-old deceased donor within 100 miles with organ arrival time at 25+ hours of Cold Ischemic Time. While this offer was intended to be allocated in waitlist order, it is not appropriate for waitlist patient #1 (30 years old) but would be accepted for waitlist patient #4 (68 years old). This scenario would avoid potential organ discards and provide a life-changing organ to a waitlist patient.

How should CMS account for organs AOOS in the achievement domain? Should CMS adjust the counting of any deceased donor transplants performed on organs AOOS?

Incorporating organs AOOS within the achievement domain is premature pending clearly defined CMS parameters related to AOOS standards, operations, and policing. Until CMS has a mechanism to govern this practice, it should not impact achievement scores. We look forward to reviewing CMS' proposed methodology for organs AOOS in future rulemaking and providing input on performance measures at that time.

How should CMS account for organs AOOS in the efficiency domain? Should CMS adjust scoring in the numerator or denominator of the metric to account for this?

Again, we believe **it is premature to account for organs AOOS in performance measures** pending clearly defined CMS parameters related to AOOS standards, operations, and policing. Until CMS has a mechanism to govern this practice, it should not impact efficiency scores. We look forward to reviewing CMS' proposed methodology for organs AOOS in rulemaking and providing input on performance measures at that time.

Should kidney transplant waitlist patients be notified about a transplant hospital bypassing them on the match run for a patient who is lower on the match run? What is the right way to inform kidney transplant waitlist patients about this occurring and how does that align with the organ offer transparency provisions described elsewhere in this proposed rule or the IOTA Model? How should CMS monitor that this has occurred?

No**, assuming CMS implements clear guidelines for organ AOOS, OPOs and Transplant Centers should**

[9] Small Hubs receive 0.05 to 0.25 percent of the annual U.S. Commercial enplanements. https://www.faa.gov/airports/planning_capacity/npias/current

[10] IAIM SRTR Data Report: 07/01/2024 to 06/30/2025 (release date January 6, 2026, and based on data available October 31, 2025) – Nationally, Cold Ischemic Time "Shared" offer acceptance is 53.2% for 12-21 hours vs. 33.6% for 22-31 hours. Logistics impacts IAIM is un

be allowed to use the AOOS process without waitlist patient notification. Such notification would not further enlighten the patient about the allocation process or their individual status on the list but rather cast doubt and suspicion on the allocation process and their providers and increase anxiety as their wait continues.

We are pleased to provide input on this proposed rule and its impact on Iowa Methodist Medical Center, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

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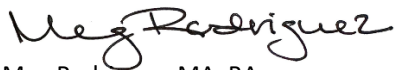

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