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CMS Finalizes Mandatory Kidney Transplant Payment Model to Enhance Access to Transplants for ESRD Patients

On November 26th, the Centers for Medicare & Medicaid Services (CMS) released the Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model final rule. This rule was accompanied by a fact sheet and a press release. See the model summary here. The rule finalizes a new mandatory payment model, the IOTA Model, which will subject participating kidney transplant hospitals to upside and downside risk based on the number of transplants they perform, the efficiency of their matching process, post-transplant success rates, and certain quality measures.

This final rule also includes standard provisions that will apply to the Radiation Oncology (RO) Model, the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) model, and all mandatory Innovation Center models with first performance periods starting on or after January 1, 2025. These provisions cover beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, data and intellectual property rights, monitoring and compliance, remedial actions, CMS's authority to terminate models, limitations on review, and various provisions regarding bankruptcy and other notifications, as well as the reconsideration review process.

The IOTA Model will begin on July 1, 2025, and end on July 30, 2031.

This final rule is scheduled to be published in the *Federal Register* on December 4, 2024. The rule will be effective 30 days after publication of the final rule on January 3, 2025.

OVERVIEW

The IOTA Model aims to increase kidney transplants for patients with ESRD by using performance-based incentive payments, including both upside and downside risk payments, for participating transplant hospitals. These incentives are designed to promote greater utilization of available donor kidneys, foster investments in value-based care, ensure equitable transplant practices, and enhance collaboration to address patients' medical and non-medical needs. CMS anticipates that increasing the number of kidney transplants for ESRD patients on participating hospitals' waitlists will lower Medicare expenditures by reducing dialysis costs and avoidable healthcare utilization, while also improving the quality of life for these patients.

The IOTA Model will measure participants' success in kidney transplants across three different domains: quality, achievement, and efficiency. Participants will be scored in these domains and receive payment from or owe payment to CMS based on their scores. Similar to the recently finalized Transforming Episode Accountability Model (TEAM), the IOTA Model will ease the transition to value-based care by providing all participants with a one-year period with no downside risk. The model will not affect existing Medicare Inpatient Prospective Payment System (IPPS) payments for kidney transplants provided to Medicare beneficiaries.

IOTA payments and recoupment will be determined solely by the volume of transplants where Medicare was the primary or secondary payer. However, IOTA participants' scores across the different domains will be based on all eligible patients, regardless of the payer. Eligible patients include individuals aged 18 or older who are registered on a waitlist with an IOTA participant or who received a kidney transplant from an IOTA participant during the performance period.

Although CMS originally proposed that the IOTA Model would begin on January 1, 2025, and end on December 31, 2030, the agency has revised these dates in response to stakeholder feedback. The model will now start on July 1, 2025, and conclude on June 30, 2031, resulting in a six-year performance period consisting of six individual performance years (PYs).

CMS SELECTS 103 KIDNEY TRANSPLANT HOSPITALS FOR IOTA MODEL PARTICIPATION

CMS used stratified random sampling to select approximately 50 percent of the donation service areas (DSA)[1] in the country and all eligible transplant hospitals in those areas with an active kidney transplant program to participate in the IOTA Model. This resulted in 103 kidney transplant hospitals being selected for participation in the model.[2] The remaining DSAs and their hospitals will serve as the comparison group for evaluation. Hospitals were eligible for selection if they performed at least 11 adult kidney transplants annually, regardless of payer type, during the three-year period from July 1, 2021, to June 30, 2024, and if at least half of their total kidney transplants were performed on adults.

BASED ON MODEL PERFORMANCE, IOTA PARTICIPANTS MAY FACE UPSIDE OR DOWNSIDE RISK

Participants will be able to score up to 100 points across the three domains. Participants who score above 60 will receive payments from CMS. Final performance scores below 60 in PY 1 and scores between 41 and 59 in PYs 2 through 6 will place participants in the neutral zone, meaning they will not receive a payment or owe a recoupment. Starting in PY 2, participants who score below 40 will owe a recoupment to CMS. Both the upside and downside risk payments will be

[1] A map of DSAs can be found here.
[2] The list of participating transplant hospitals can be found here.

paid/recouped in a lump sum following the PY. The maximum a participant could earn per Medicare FFS transplant under the model would be $15,000 (as opposed to $8,000 as proposed), while the maximum a participant could owe per transplant would be $2,000.

CMS will calculate the upside risk payment using the following formula:

> *((Final performance score – 60)/40) x $15,000 x Total number of kidney transplants performed by the participant to attributed patients with Medicare as a primary or secondary payer*

So, if a hospital scored 80 and performed 30 eligible transplants, their payout would be:

> *((80 – 60)/40) * $15,000 * 30 = (20/40) * $15,000 * 30 = $225,000*

CMS will calculate the downside risk payment using the following formula:

> *((Final performance score – 40)/40) * -$2,000 * Total number of kidney transplants performed by the participant to attributed patients with Medicare as a primary or secondary payer*

So, if a hospital scored 30 and performed 30 eligible transplants, they would owe CMS:

> *((30-40)/40) * -$2,000 * 30 = (10/40) * -$2,000 * 30 = $15,000*

To allow for sufficient Medicare kidney transplant claims runout, CMS will conduct preliminary scoring and payment calculations for each PY three to six months after its conclusion. Participants will be notified of their score and payment within five to nine months following the end of the PY and will have 30 days to review the scores before receiving their final performance results. At the end of this review period, upside payments and demand letters for downside payments will be issued to participants.

IOTA PARTICIPANTS' PERFORMANCE WILL BE MEASURED ACROSS THREE DOMAINS

The IOTA Model will measure participants across three different domains: achievement, efficiency, and quality. Medicare claims and administrative data about beneficiaries, providers, suppliers, as well as data from the Organ Procurement Transplant Network (OPTN), will be used to measure participant performance in these domains. The summed scores in these domains will determine whether a hospital receives a payment from CMS, owes a payment to CMS, or is a neutral zone where payment is not received or owed. The total points available across each domain, and the measures used to assess performance in these domains, are below:

Table 1. IOTA Domain Total Available Points and Measures

Domain	Total Points	Metrics in Domain
Achievement	60	Number of adult transplants
Efficiency	20	Organ offer acceptance rate ratio
Quality	20	Post-transplant composite graft survival rate
Totals	**100**	-

Achievement

The achievement domain will make up the majority (60 percent) of the total points a participant would be eligible for. This domain will award points to hospitals based on how they performed against a total transplant target set by CMS for each PY. CMS had proposed to set the transplant target as the highest number of deceased or living donor kidney transplants performed during the baseline years trended forward by the national growth rate. Instead, CMS will assign hospitals a transplant target equal to the average number of transplants performed during the baseline years trended forward by the national growth rate.

CMS finalizes a lower maximum performance threshold of 125 percent, reduced from 150 percent as proposed. The scoring system has also been modified to increase the number of performance bands from five to eight, narrowing the range of results within each band.[3] These changes are intended to better differentiate participants and improve comparisons.

Participants who performed less than 75 percent of their target will receive a score of zero. Participants scoring at or above 125 percent of their target will receive the full 60 points. The full range of available scores can be seen below:

Table 2. Achievement Domain Scoring

Performance Relative to Transplant Target	Points Earned
125% of transplant target or higher	60
120% to less than 125% of transplant target	55
115% to less than 120% of transplant target	50
105% to less than 115% of transplant target	40
95% to less than 105% of transplant target	30
85% to less than 95% of transplant target	20
75% to less than 85% of transplant target	10
Less than 75% of transplant target	0

CMS had also proposed a health equity performance adjustment, which was not finalized. The points allocated for this domain were updated to make the thresholds for achieving top performance more attainable.

[3] See Table 3 on page 181 of the unpublished final rule for the proposed achievement domain scoring.

Efficiency

The efficiency domain will be worth up to 20 total points and will evaluate participants based on their organ offer acceptance rate ratio. This ratio is calculated using the Organ Procurement and Transplantation Network's (OPTN) offer acceptance rate ratio performance metric.

This metric divides the number of kidney transplant organs accepted by each participant by a risk adjusted measure of expected organ acceptances. The expected organ acceptances will account for factors such as whether the kidney was biopsied, how long the candidate has been on dialysis, and the distance between the donor hospital and the transplant center. The percent chance of acceptance will be calculated for each transplant offer the participant received during a PY, and these summed percentages would determine the final expected organ acceptances that participants would be measured against. For a list of organ offers that would be excluded from this calculation, see Table 6 on page 225 of the unpublished final rule.

Under this measure, participants will receive two scores, an achievement score measuring their current level of performance, and an improvement score measuring how that performance had improved over time. Participants will receive the higher of the two scores as their final score for the efficiency domain.

The achievement score is based on the participant's performance on organ offer acceptance rate ratio relative to the national ranking, which includes all eligible transplant hospitals. The table below shows the bounds for this score.

Table 3. Efficiency Domain – Achievement Score

Performance Relative to National Ranking	Points Earned
Greater than 80th percentile	20
Equal to the 60th percentile and less than the 80th percentile	15
Equal to the 40th percentile and less than the 60th percentile	10
Equal to the 20th percentile and less than the 40th percentile	6
Less than the 20th percentile	0

The improvement score is based on a comparison of the participant's organ-offer acceptance rate ratio during the PY to the participant's improvement benchmark rate. If a participant's organ-offer acceptance rate ratio is greater than or equal to the improvement benchmark rate, the participant will be awarded 15 points for the efficiency domain. If the rate is equal to or less than the participant's organ-offer acceptance rate ratio in the third baseline year for the respective PY, zero points will be awarded. CMS will use the equation on page 553 of the unpublished final rule in scenarios where the organ-offer acceptance rate ratio is greater than the participant's organ-offer acceptance ratio in the third baseline year for that respective PY but less than the improvement benchmark rate.

Quality

The quality domain will be worth up to 20 points, with all of the points being based off a participant's composite graft survival rate. CMS had proposed that ten points would be based off

of a quality measure set, but did not finalize this proposal.

Composite Graft Survival Rate

To reward participants for positive post-transplant outcomes, CMS will allocate points based on a participant's unadjusted rolling composite graft survival rate. For PY 1, this metric will be the number of functioning grafts divided by the number of completed adult transplants. For subsequent PYs, this figure will be updated to account for any failed transplants from past PYs. In response to comments, CMS will consider a risk adjustment methodology for this measure in future years but is not implementing one at this time.

The following will be excluded from the number of observed functioning grafts: graft failure, re-transplant, death, pediatric patients, and offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

Participants will receive points based on their performance against all hospitals eligible for IOTA, regardless of whether they were selected for the model. The bands have been revised in the final rule and the point values have increased to reflect the removal of the quality measure set. The point distribution can be seen in Table 4 below.

Table 4. Composite Graph Survival Rate Point Distribution

Performance Relative to Target Bounds	Points Earned
Greater than or equal to 80th percentile	20
Equal to the 60th percentile and less than the 80th percentile	18
Equal to the 40th percentile and less than the 60th percentile	16
Equal to the 20th percentile and less than the 40th percentile	14
Equal to the 10th percentile and less than the 20th percentile	12
Less than the 10th percentile	0

CMS Does Not Finalize Quality Measure Set

CMS had initially proposed to require IOTA participants to report three quality measures, but none were finalized. In future rulemaking, CMS may propose additional quality measures, potentially focusing on health-related quality of life (HRQoL) for kidney transplant recipients or pre-transplant care processes.

AGENCY FINALIZES ADDITIONAL TRANSPARENCY AND HEALTH EQUITY REQUIREMENTS FOR IOTA PARTICIPANTS

CMS has outlined additional requirements and opportunities for IOTA participants beyond the core components, including transparency and health equity.

Transparency

Often, patients are unsure if they qualify for a kidney transplant at a given kidney transplant hospital. To increase transparency for beneficiaries, CMS finalizes its proposal to require IOTA participants to publish, on a public website, the criteria they use when determining whether or

not to add a patient to the kidney transplant waitlist. This ensures that patients have clear and accessible information when determining eligibility.

Health Equity

CMS initially proposed that beginning in PY 2 of the model, participants would be required to submit a health equity plan (HEP) to CMS. However, in the final rule, CMS has decided that submitting a HEP will be optional for IOTA participants, rather than mandatory. The HEP will identify health disparities amongst the IOTA Model participant's patient population and identify a course of action to address them. The goal is to promote better equity in healthcare access and outcomes for all patients.

CMS OUTLINES APPROACH TO DATA SHARING TO ENHANCE MODEL PERFORMANCE AND IMPROVE PATIENT OUTCOMES

CMS finalizes its proposal to share beneficiary-identifiable data with IOTA Model participants, enabling them to access Medicare data on attributed patients to improve transplant readiness, post-transplant outcomes, and overall care coordination. This data will include beneficiary claims information, such as Parts A, B, and D claims data, which IOTA Model participants will use to evaluate performance, conduct quality assessments, and coordinate care across various providers. IOTA participants must comply with Health Insurance Portability and Accountability Act of 1996 (HIPAA) and sign a data-sharing agreement to protect patient privacy and confidentiality.

Medicare beneficiaries will be notified of the data sharing and given the opportunity to opt out of having their data shared. If a beneficiary opts out, their data will not be shared with IOTA Model participants, though they cannot opt out of sharing de-identified data or other attribution-related information. CMS clarifies that CMS will limit the data shared to the minimum necessary for health care operations under the IOTA Model.

CMS TO PERMIT IOTA PARTICIPANTS TO ENGAGE IN OTHER INNOVATION CENTER MODELS AND CMS PROGRAMS

CMS explains that the IOTA Model is expected to overlap with other CMS programs, models, and departmental regulatory efforts. For example, a Medicare beneficiary attributed to an IOTA participant may also be assigned or attributed to another Innovation Center model or CMS program. Overlap could also occur at the provider level, whether individual or organizational. CMS anticipates that the IOTA Model will intersect with programs such as the Kidney Care Choices (KCC) Model, the ETC Model, the Medicare Shared Savings Program, the ACO Realizing Equity, Access, and Community Health (REACH) Model, and the Hospital Value-Based Purchasing (VBP) Program. Consequently, CMS finalizes its proposal to allow IOTA participants to participate concurrently in IOTA and other Innovation Center models and CMS programs. The agency will continue to monitor the transplant ecosystem and other CMS departments to identify and address any unintended consequences in future rulemaking.

TO PROTECT BENEFICIARIES, CMS FINALIZES REQUIREMENTS TO LIMIT THE POTENTIAL FOR FRAUD AND ABUSE

CMS finalizes its proposal to require IOTA Model participants to notify beneficiaries and patients of their participation in the model. To support this, CMS intends to provide a mandatory notification template for participants to use. Additionally, CMS is finalizing the requirement for IOTA participants to display a notice outlining beneficiary rights and protections at each office or facility location.

Furthermore, CMS finalizes its proposal that beneficiaries cannot opt out of being attributed to an IOTA participant. However, they retain the freedom to select a different kidney transplant hospital or other providers for their care.

CMS FINALIZES MONITORING AND COMPLIANCE PRACTICES TO ENSURE MODEL INTEGRITY AND SAFEGUARD PATIENT CARE

The agency finalizes several proposals related to enhancing the monitoring and compliance processes for the IOTA Model. These monitoring activities will include documentation requests, data audits, patient interviews, and site visits to ensure adherence to model terms and safeguard patient care. CMS also aims to track organ allocation practices to ensure that participants are not compromising patient care or model results to manipulate payments. Monitoring will be conducted using Medicare claims data and CMS notes it has the authority to intervene if necessary to maintain program integrity, including adjusting payments or requiring refunds if discrepancies are found.

Regarding site visits, CMS will require IOTA participants to cooperate with periodic visits with at least 15 days' advance notice. If urgent concerns arise regarding patient safety or program integrity, unannounced visits may be conducted. CMS clarifies that site visits are intended to evaluate compliance and ensure that medically necessary services are provided without discrimination.

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