Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5544-P) Proposed Rule Summary

I. Introduction[1]

On December 11, 2025, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register (90 FR 55342) a proposed rule that would update and revise the Increasing Organ Transplant Access (IOTA) Model. 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. The IOTA Model is testing whether performance-based incentives paid to or owed by participating kidney transplant hospitals can increase access to kidney transplants for kidney transplant waitlist patients, while preserving or enhancing quality of care and reducing Medicare expenditures.

CMS has selected 103 kidney transplant hospitals to participate in the IOTA Model and will be measuring and assessing the participating kidney transplant hospitals' performance during each performance year (PY) across three performance domains: achievement, efficiency, and quality. The IOTA Model was established through notice and comment rulemaking, finalized in the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Final Rule (2024 Final Rule), CMS-5535-F, published December 4, 2024. In the 2024 Final Rule, CMS signaled that there were several policies that could be addressed through future rulemaking including: the addition of a risk-adjustment methodology in the calculation of the composite graft survival rate, the addition of transplants furnished to Medicare Advantage beneficiaries to the definition of Medicare kidney transplants, and the addition of transparency requirements, among other changes.

The deadline for public comment is February 9, 2026.

[1] For simplification, summary headers do not match the proposed rule headings.

II. Proposed Changes to the IOTA Model

A. IOTA Participants

In the 2024 Final Rule, CMS finalized that a kidney transplant hospital is eligible to be selected as an IOTA participant if it meets both of the following criteria: (1) The kidney transplant hospital annually performed 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, in each of the baseline years; and (2) the kidney transplant hospital annually performed more than 50 percent of its kidney transplants on patients 18 years of age or older in each of the baseline years.

1. Modifying the Eligible Kidney Transplant Hospital Criteria

Per section 1835(d) of the Social Security Act (the Act) as codified in 42 CFR 411.6, Medicare does not pay for services furnished by a Federal provider of services or other Federal agency, nor does Medicare pay for services that are paid for directly or indirectly by a government entity, with only limited exceptions. CMS proposes to modify the eligible kidney transplant hospital criteria to exclude Department of Veteran's Affairs (VA) medical facilities and military medical treatment facilities (MTFs) from the IOTA Model for PYs 2 through 6. Specifically, CMS proposes at §512.412(a)(3) to exclude kidney transplant hospitals that are a MTF or VA medical facility from being eligible to participate in the IOTA Model. CMS proposes at §512.402 to define a "VA medical facility" using the definition in VA regulations at 38 CFR 17.1505 to mean a VA hospital, a VA community-based outpatient clinic, or a VA health care center, any of which must have at least one full-time primary care physician, but not a Vet Center or Readjustment Counseling Service Center. Additionally, CMS proposes at §512.402 to define a "military medical treatment facility (MTF)" as it is currently defined at 10 U.S.C. §1073c(j)(3) to mean: (1) any fixed facility of the Department of Defense that is outside of a deployed environment and used primarily for health care; and (2) any other location used for purposes of providing healthcare services as designated by the Secretary of Defense.

CMS seeks comment on its proposal at §512.412(a)(3) to exclude kidney transplant hospitals that are a MTF or VA medical facility as eligible to participate in the model. CMS also seeks comments on its proposed definitions of MTF and VA medical facility at proposed §512.402**.**

2. Modifying the Low Volume Threshold

In the 2024 Final Rule, CMS established a low volume threshold requiring kidney transplant hospitals to have performed 11 or more kidney transplants for patients aged 18 years or older annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model, which as designed to protect beneficiary confidentiality and align with minimum CMS data display standards while ensuring statistical significance. However, in response to some IOTA participants expressing concern about their ability to participate in the model and CMS' experience in operating the model, CMS believes it is necessary to reevaluate the low volume threshold. CMS proposes to raise the low volume threshold from a minimum of 11 kidney

transplants performed annually during each of the baseline years to a minimum of 15 kidney transplants performed annually during each of the baseline years.

CMS alternatively considered higher low volume thresholds, such as 20 kidney transplants or 25 kidney transplants performed for patients aged 18 years or older annually, regardless of payer, during each of the baseline years. CMS believes the proposed low volume threshold of 15 kidney transplants or more performed to patients aged 18 years or older annually best balances excluding the smallest kidney transplant hospitals, while still being able to ensure that the model has sufficient statistical power to be able to test the model. CMS states, however, that the proposed update would only result in the removal of one IOTA participant as of the model start date, while higher thresholds would result in additional IOTA participants being removed, which could diminish the ability to evaluate the model.

CMS seeks comment on its proposal to adjust the low volume threshold to 15 kidney transplants at §512.412(a)(1). CMS also seeks public comment on the alternatives considered.

B. Performance Assessment

In the 2024 Final Rule, CMS finalized a policy to assess IOTA participant performance each PY in the quality domain on post-transplant outcomes using the composite graft survival rate. While the model performance period has begun, CMS indicated that for certain policies, such as the inclusion of a risk-adjustment methodology when calculating the composite graft survival rate to account for the complexities of donors and recipients, and their associated risks, CMS would go through rulemaking in the future to promulgate new or updated policies that would be finalized after the model start date. CMS is proposing updates to the composite graft survival rate metric that would include modifications to the risk adjustment methodology, the exclusion and inclusion criteria, and the allocation of points awarded for performance.

1. Adding A Risk-Adjustment Methodology to Calculate the Composite Graft Survival Rate

Since publication of the 2024 Final Rule, many IOTA participants have urged CMS to include a risk-adjustment methodology in the composite graft survival rate calculation. To address this concern, CMS is proposing at §512.428(b)(2) to include a risk-adjustment methodology in the composite graft survival rate calculation. CMS believes that accounting for case-mix differences is important because it recognizes that some IOTA participants care for older or sicker kidney transplant patients who have lower graft survival rates. Specifically, CMS proposes at §512.428(b)(2)(i)(A) and (B) that CMS would, in accordance with §512.428(b)(1) through (3), risk-adjust the composite graft survival rate to account for multiple transplant recipient and donor characteristics. CMS states that at a minimum this risk adjustment would incorporate transplant recipient and donor characteristics described in the table below. CMS states that the proposed transplant recipient and donor characteristics represent well-established, non-modifiable predictors that significantly influence graft survival independent of care quality.

Characteristics to be considered in the risk adjustment of the composite graft survival rate	
Transplant recipient characteristics	Age, Sex, Kidney function (eGFR/creatinine), Diabetes status, Hypertension with or without cardiovascular disease, Human leukocyte antigen (HLA) mismatch, and Plasma renin activity (PRA) levels.
Donor characteristics	Age, Sex, Kidney function (eGFR/creatinine), Diabetes status, Hypertension history with or without cardiovascular disease, Cardiovascular disease, Human leukocyte antigen (HLA) mismatch, Plasma renin activity (PRA) levels, Cause of death, and Donation after cardiac death.

CMS proposes at §512.428(b)(2) to analyze the transplant recipient and donor characteristics as specified above and then apply a risk score to each individual IOTA transplant patient based on this analysis. CMS also proposes to use the calculated composite graft survival rate risk scores identified to—

- Normalize the composite graft survival rate outcome to control for differences in kidney transplant patient risk; and
- Adjust the composite graft survival rate, based on the normalized composite graft survival rate outcome.

CMS also considered other approaches, including the adoption of the Scientific Registry of Transplant Recipients (SRTR) risk-adjustment methodology, a risk-adjustment model that utilizes a Cox regression model that addresses time-to-event outcomes,[2] a direct standardization risk-adjustment approach, an indirect (observed-to-expected ratios) risk-adjustment approach, a hierarchical logistic regression approach, and a machine learning-based risk adjustment methodology.[3]

CMS seeks comments on its proposed composite graft survival rate risk-adjustment methodology at proposed §512.428(b)(2). CMS also seeks comment on what transplant recipient and donor characteristics, infectious disease status or other medically complex factors, transplant recipient comorbidity burden, and immunological risk factors would be significant and clinically appropriate to include in the proposed risk-adjustment methodology for the composite graft survival rate metric.

CMS also seeks comment on the alternatives considered. CMS states that although it is not proposing to include a risk-adjustment methodology that also accounts for time-to-event data, it seeks comment on whether a risk-adjustment methodology that considers transplant recipient and donor characteristics in addition to time-to-event data would be appropriate for calculating the composite graft survival rate in the quality domain and the best approach to use. CMS also seeks comments on whether the proposed risk-adjustment methodology should also include a time-to-event model when calculating the composite graft survival rate in the quality domain.

[2] Cox regression, formally designated as Cox proportional hazards regression, constitutes a statistical methodology employed to examine the relationship between the time to event occurrence and one or more predictor variables. This analytical approach represents a robust statistical tool for investigating survival data, particularly when addressing time-to-event outcomes

[3]Each of these options are discussed in detail in the preamble of the proposed rule (90 FR 57607-57608).

2. Excluding Multi-Organ Transplants from the Composite Graft Survival Rate Exclusion and Inclusion Criteria

In the 2024 Final Rule (89 FR 96364), CMS finalized inclusion and exclusion criteria for the numerator and denominator when calculating the composite graft survival rate at §512.428(b)(1)(iii) and (iv)(A). Since publication, many IOTA participants have asked CMS to clarify whether multi-organ transplants are included in both the numerator and denominator when calculating the composite graft survival rate. CMS clarified that multi-organ transplants are included in the numerator but not the denominator. Since CMS clarified that multi-organ transplants are included in the calculation of the composite graft survival rate, many IOTA participants have urged CMS to exclude them from the metric due to the additional complexity of multi-organ transplantation.

CMS proposes to update its regulation at §512.428(b)(1)(iii)(E) to exclude multi-organ transplants (except for kidney/pancreas transplants) from the numerator. As a result, CMS is also proposing to update the provision at §512.428(b)(1)(iv)(A) to read as follows: When calculating the composite graft survival rate, CMS only includes single-organ kidney transplants and kidney/pancreas transplants for transplant recipients who are 18 years of age and older at the time of the kidney transplant or kidney/pancreas transplant in the number of kidney transplants performed by the IOTA participant during each PY in the denominator. For purposes of the model, CMS proposes at §512.402 to define "single-organ kidney transplant" as a procedure in which a kidney alone is surgically transplanted from a living or deceased donor.

CMS states that it considered retaining the inclusion of multi-organ transplantation in the calculation of the composite graft survival rate and solely revising the text of the regulation for clarification purposes. CMS also considered excluding all multi-organ transplants, including kidney/pancreas transplants, from the composite graft survival rate due to the increased surgical complexity and perioperative complications. CMS believes, however, that the improved clinical outcomes for kidney/pancreas transplants compared to kidney transplantation alone for Type 1 Diabetes Mellitus patients outweighed the added surgical complexity and potential perioperative complications.

CMS seeks comment on its proposed definition of single-organ kidney transplant and whether it should include multi-organ transplants in the numerator and denominator and which multi-organ transplants should CMS include or exclude. CMS also seeks comment on the alternatives considered.

3. Updating the Allocation of Points Awarded for Performance on the Composite Graft Survival Rate

In the 2024 Final Rule (89 FR 43518) that established the IOTA Model, CMS acknowledged commenters' concern that allocation of points unfairly penalizes transplant hospitals that accept higher-risk patients and suggested modifications including lowering the threshold for maximum points from the 80th to 60th percentile for IOTA participants (89 FR 96365). In response to comments, CMS finalized an alternate scoring methodology, such that IOTA participants would

be awarded points based on the national quintiles, as outlined in Table 1 in the proposed rule (reproduced below).

Table 1: Composite Graft Survival Rates Scoring	
Performance Relative to National Ranking	**Points Earned**
80th Percentile ≤	20
60th ≤ and < 80th Percentile	18
40th ≤ and < 60th Percentile	16
20th ≤ and < 40th Percentile	14
10th ≤ and < 20th Percentile	12
< 10th Percentile	10

CMS states that upon further review of its methodology, it is proposing to modify the composite graft survival rate scoring methodology to allow for a more even scoring distribution for IOTA participants. Points earned would be based on the IOTA participants' performance on the composite graft survival rate relative to national ranking, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants, as outlined in Table 2 (reproduced below). Points would continue to be awarded based on national quintiles. Points would be awarded in the following manner:

- IOTA participants in the 80th percentile and above, 20 points.
- IOTA participants in the 60th to below the 80th percentile of performers, 15 points.
- IOTA participants in the 40th to below the 60th percentile of performers, 10 points.
- IOTA participants in the 20th to below the 40th percentile of performers, 5 points.
- IOTA participants who are below the 20th percentile of performers, 0 points.

Table 2: Proposed Composite Graft Survival Rate Scoring			
Performance Relative to National Ranking	**Lower Bound Condition**	**Upper Bound Condition**	**Points Earned**
80th Percentile relative to target OR for comparison	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	5
20th Percentile	N/A	Less than 20th percentile	0

CMS also considered applying a two-scoring system in which it would determine an achievement score and improvement score and award the point equivalent to the higher value between the two scores; similar to the organ offer acceptance rate ratio scoring methodology. However, CMS states it chose not to propose this methodology because it still had concerns over its ability to measure improvement year-over-year due to potentially small numbers.

CMS seeks comment on its proposed composite graft survival rate scoring methodology for purposes of assessing quality domain performance for each IOTA participant. CMS also seeks comment on whether a two-scoring system methodology would be appropriate for the composite graft survival rate and the best approach for measuring improvement. Additionally, CMS seeks comment on whether there is a scoring methodology on the composite graft survival rate that recognizes IOTA participants whose post-transplant outcomes are at an acceptable level and how to define an acceptable level (for example, within one standard deviation of the national risk-adjusted rate or some other way).

C. Payment

As finalized in the 2024 Final Rule, each IOTA participant's final performance score will determine whether: (1) CMS will pay an upside risk payment to the IOTA participant; (2) the IOTA participant will fall into a neutral zone where no performance-based incentive payment will be paid to or owed by the IOTA participant; or (3) the IOTA participant will owe a downside risk payment to CMS. For a final performance score greater than 60, CMS will apply the formula for the upside risk payment, which will be equal to the IOTA participant's final performance score minus 60, then divided by 40, then multiplied by $15,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare fee-for-service (FFS) as their primary or secondary payer during the PY. Final performance scores below 60 in PY 1 and final performance scores of 40 to 60 (inclusive) in PYs 2 through 6 will fall in the neutral zone where there will be no payment owed to the IOTA participant or CMS. There is no downside risk payment for PY 1 of the IOTA Model.

This section includes several proposals related to payment policies in the IOTA Model.

1. Comment Solicitation on Whether to Include MA Enrollees Within the IOTA Model

In CMS' initial proposal in the 2024 Proposed Rule (89 FR 43570), CMS considered including beneficiaries with Medicare Advantage (MA) in the definition of Medicare kidney transplants. CMS, however, decided to finalize the policy as proposed as it did not believe that the additional incentive effects from including MA enrollees in the calculation for upside and downside risk payments were necessary at that point to provide sufficient incentive to test the model. CMS noted its plan to further engage with MA plans to think about the incentives in the IOTA Model and those set up by MA plans.

CMS seeks comment on whether it should include MA enrollee transplants in the calculation for upside risk payments and downside risk payments. CMS also seeks comment on its consideration to update the definition of Medicare kidney transplants at §512.402 to include attributed patients with MA enrollment, to further the incentive effects of the IOTA Model and in recognition of the growth of MA enrollment relative to Medicare FFS.

CMS notes that Medicare FFS enrollment of the total ESRD population is currently about 45 percent and is projected to drop to about 40 percent by 2028. This means that updating the definition of Medicare kidney transplant to include MA enrollees would increase the maximum potential upside risk payments. Under this approach, CMS could decrease the maximum upside risk payment from $15,000 to $10,000 per Medicare kidney transplant. CMS analyses project that the decreased upside risk payment multiplier and increased number of kidney transplants that upside and downside risk payments would apply to under such an approach would approximately offset each other and approximately have a net zero impact on model savings from this combination of provisions. **CMS seeks comment on its consideration to decrease the maximum upside risk payment from $15,000 to $10,000 per Medicare kidney transplant should CMS update the definition of Medicare kidney transplant to include MA beneficiaries.**

CMS is also concerned about whether the payments made under such an approach could affect the contracting relationship between a Medicare Advantage organization (MAO) and the IOTA participant. **CMS seeks feedback from both IOTA participants and from MAOs about any potential effect that inclusion of beneficiaries enrolled in MA plans in the definition of Medicare kidney transplants in the IOTA Model could have on their contracting relationships.** Pursuant to the non-interference clause in section 1854(a)(6)(B)(iii) of the Act, CMS does not interfere in payment arrangements between MAOs and their contracted providers. At the same time, CMS states that it is interested in the potential in achieving greater alignment between MA and Medicare FFS payment methodologies.

CMS solicits comments from a broad range of stakeholders and interested parties, including MAOs, beneficiary advocates, healthcare providers, and industry experts. **Specifically, CMS seeks public comment on the following questions:**

- What are any innovative transplant-related strategies being tested by MAOs?
- What are the anticipated effects that implementation of this contemplated policy modification would have on the kidney transplant strategic initiatives currently under consideration by MAOs?
- How does the growth of MA compared to Medicare FFS affect participation and incentives in the IOTA Model?
- What do MA plans consider as their role in the kidney transplant process?
- What performance metrics do MA plans consider when evaluating kidney transplant hospitals?
- What performance metrics are the most important for a kidney transplant hospital?
- What are kidney transplant hospitals' experiences with kidney transplant performance metrics from private insurers and MAOs, outside of their experience with the IOTA Model?
- How do the IOTA Model performance metrics play a role in the relationship between an MA plan and a contracted provider?
- If any, what are potential effects that including MA enrollees in the model could have on a contracting relationship between providers and MA plans (for example, negotiation of terms)?
- If any, what are potential unintended consequences of including MA enrollees on utilization management tools employed by MAOs?
- Would an MA plan consider implementing similar performance metrics to those included in the IOTA Model?
- Under what circumstances is it appropriate for CMS to consider directly incentivizing a behavior change from a provider contracted in an MA plan?

2. Determine Final Performance Score Range Category

In the 2024 Final Rule (89 FR 96384), CMS finalized using the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone at §512.430(a), as illustrated in Table 3 (reproduced below). Additionally, CMS finalized the definitions of downside risk payment, upside risk payment, and neutral zone at §512.402.

Table 3. Performance-Based Payments by Final Performance Score			
Final Performance Score	**PY 1**	**PY 2 – 6**	
60-100	Upside Risk Payment	Upside Risk Payment	
41-59 (Inclusive)	Neutral Zone	Neutral Zone	
0 - 40	Neutral Zone	Downside Risk Payment	

Since publication of the 2024 final rule, some IOTA participants have expressed confusion about final performance scores of 40 points and 60 points. CMS is proposing to clarify the endpoints where an IOTA participant could receive an upside risk payment, be in the neutral zone, or receive a downside risk payment. As noted previously, there is no downside risk payment in PY 1. Specifically, CMS proposes at §512.430(b) to clarify that (1) if in PYs 1-6, the IOTA participant's final performance score is above 60 points, the IOTA participant qualifies for an upside risk payment; (2) for PYs 2 through 6, if an IOTA participant's final performance is between 40 to 60 points (inclusive), the IOTA participant qualifies for the neutral zone; and (3) if an IOTA participant's final performance score is below 40 points in PYs 1 through 6, the IOTA participant qualifies for a downside risk payment.

CMS seeks comment on its proposals to clarify the appropriate final performance score ranges for an IOTA participant to be eligible to receive an upside risk payment, be in the neutral zone, or receive a downside risk payment.

3. Downside Risk Payment

Currently, IOTA Model regulations stipulate that IOTA participants must remit the downside risk payment to CMS in a single payment at least 60 days after the date on which the demand letter is issued. CMS is proposing to modify the policy previously finalized in the 2024 Final Rule such that IOTA participants must remit the downside risk payment to CMS in a single payment within 60 days after the date on which the demand letter is issued. If full payment is not received by CMS within 60 days after demand is made, the remaining amount owed will be considered a delinquent debt.

CMS seeks comment on its proposal at proposed §512.430(d)(6)(ii) to clarify that full payment of a downside risk payment must be received within 60 days after the demand is made and that it will be considered delinquent debt if not received within that time period.

4. Extreme and Uncontrollable Circumstances

Finally, in the 2024 Final Rule, CMS established an Extreme and Uncontrollable Circumstance (EUC) payment policy recognizing that events may occur outside the purview and control of the IOTA participant that may affect their performance in the model. Under the current provision in the IOTA Model, CMS applies determinations made by the Quality Payment Program (QPP) with respect to whether an EUC has occurred, and the areas impacted during the PY. As currently finalized, in the event of an extreme and uncontrollable circumstance, as determined by the QPP, CMS may reduce the downside risk payment, if applicable, prior to recoupment. CMS determines the amount of the reduction by multiplying the downside risk payment by both the

percentage of total months during the PY affected by the EUC and the percentage of attributed patients who reside in an area affected by the EUC.

CMS recognizes that QPP policies may not be appropriate for the IOTA Model due to different payment calculation inputs and program goals. CMS also acknowledges the limited nature of the current EUC provision to account for broader impacts that an EUC might have on an IOTA participant's ability to perform in the model, which only potentially reduces downside payments without accounting for changes in model inputs or reporting periods that may affect an IOTA participant's performance score. Therefore, this proposed rule would make updates to the EUC provisions to provide CMS sole discretionary authority to do the following:

- Apply flexibilities to IOTA participants located in emergency areas during emergency periods (as defined in section 1135(g) of the Act) with Secretary-issued waivers and in counties, parishes, or tribal governments designated under major disaster declarations pursuant to the Stafford Act.
- Extend payment and reporting accommodations to IOTA participants impacted by the EUC.
- Adjust the upside risk payment or downside risk payment amount for the IOTA participant if the IOTA participant is participating in the IOTA Model when such an emergency period has been declared.

CMS seeks comment on its proposal at proposed §512.436(a)(1) to clarify how CMS will determine if an emergency situation occurs for an IOTA participant beginning in PY 2 of the Model. CMS also seeks comment about the flexibilities at proposed §512.436(b) that CMS may adjust upside or downside payments to respond to a potential emergency faced by an IOTA participant.

D. Transparency Requirements

1. Publication of Selection Criteria for Kidney Transplant Evaluations and Waitlisting

CMS finalizes in the 2024 Final Rule (89 FR 96394) that established the IOTA Model, that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1 at §512.442(a). To advance transparency for individuals seeking transplant waitlist access and to improve patient health literacy regarding transplant program evaluation processes, CMS proposes to revise §512.442(a). Specifically, CMS proposes to revise the paragraph heading at §512.442(a) to remove "transplant patient" from "Publication of transplant patient selection criteria" and to redesignate the current requirement from §512.442(a) to §512.442(a)(1). For all subsequent PYs, CMS proposes at §512.442(a)(2) that the IOTA participant must review its publicly posted criteria used for evaluating and selecting patients for addition to its kidney transplant waitlist and ensure that the information on its website is up to date by the end of each relevant PY. CMS states that it alternatively considered requiring IOTA participants to update their publicly posted patient selection waitlist criteria to ensure that this information on their websites remains current within timeframes of 30 days, 60 days, or 90 days following any modification.

CMS seeks comments in its proposals at §512.442(a)(1) and §512.442(a)(2) and the alternative considered.

CMS recognizes that the current regulations in the IOTA Model do not address publicly posting living donor selection criteria. As such, for IOTA participants performing living donor kidney transplants, CMS proposes, at §512.442(a)(3)(i), that those IOTA participants must publicly post on their websites their living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients by the end of PY 2. For all subsequent PYs, CMS proposes at §512.442(a)(3)(ii) that the IOTA participant must review its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients on its website and ensure that the information publicly posted on its website is correct by the end of each relevant PY. CMS believes requiring IOTA participants that perform living donor kidney transplants to publicly post on their website their living donor selection criteria would significantly enhance transparency in the kidney transplant system by making living donor selection criteria readily accessible to patients, families, and referring physicians, allowing them to make more informed decisions about transplant options and understand the specific requirements each IOTA participant uses to evaluate potential living donors. CMS alternatively considered requiring IOTA participants to update their publicly posted living donor selection criteria to ensure that this information on their websites remains current within timeframes of 30 days, 60 days, or 90 days following any modification.

CMS seek comments on these proposals at proposed §512.442(a)(3)(i) and (ii) and the alternative considered.

As previously suggested by commenters in the 2024 Final Rule (89 FR 96396), CMS also considered creating a standardized waitlist selection criteria template for IOTA participants to use that would include specific details of waitlist selection criteria such as absolute contraindications, financial and insurance requirements, and psychosocial factors that impact listing decisions. CMS also considered but did not propose creating a standardized living donor selection criteria template for IOTA participants to use that would be relative or absolute contraindications for donating a kidney.

CMS is seeking comment regarding whether the inclusion of such templates would be preferable and would not impose additional administrative burden upon IOTA participants. Additionally, beyond the requirements outlined in 42 CFR 482.90, CMS seeks comment on what specific requirements or specific detail should be included in standardized waitlist selection criteria or living donor selection criteria templates.

2. Publication of IOTA Participant Selection Criteria

In the Specialty Care Models final rule (85 FR 61114), CMS established certain general provisions in 42 CFR part 512 subpart A that apply to all Innovation Center models. This included that CMS would disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. The data to be disseminated would include patient de-identified

results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources.

Consistent with these provisions, in the 2024 Final Rule (89 FR 96403) that established the IOTA Model, CMS finalized its proposals to publish results from all PYs of the IOTA Model. Adding to these provisions, CMS proposes to publish IOTA participant waitlist selection criteria and the proposed living donor selection criteria on the IOTA Model website. Specifically, for each PY, CMS intends to publish waitlist selection criteria and the proposed living donor selection criteria for each IOTA participant on the IOTA Model website by the end of the second quarter of each subsequent PY. CMS states that it will finalize this requirement only if this is not redundant with other HHS guidance. CMS believes the release of this information on the IOTA Model website would address previous suggestions from commenters to provide this information in a centralized location (89 FR 96396). Lastly, CMS notes that this would supplement, not replace, the publication of selection criteria requirements in the IOTA Model.

CMS seeks comment on its proposal to post this information to the IOTA Model website, as well as the information it intends to post and the manner and timing of the posting.

3. Transparency into Kidney Transplant Organ Offers

As discussed in the 2024 Final Rule (89 FR 96397), those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no requirement for providers to discuss organ offers with their patients. As described in the 2024 Final Rule (89 FR 96397), CMS had proposed to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries[4] regarding the volume of organ offers received on their behalf while on the waitlist. Specifically, CMS proposed that for each month an organ is offered to an IOTA waitlist patient, an IOTA participant must inform the Medicare beneficiary, on a monthly basis, of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for the decline. However, following feedback from public comments that this policy would impose a significant administrative burden on IOTA participants, CMS did not finalize this transparency requirement.

Based on the feedback CMS received since publication of the 2024 Final Rule, CMS proposes an alternative approach for the model. Specifically, for PYs 3 through 6 CMS proposes at §§512.442(b) and (b)(1) that IOTA participants would be required to notify eligible IOTA waitlist beneficiaries of the number of times an organ is declined on the eligible IOTA waitlist beneficiary's behalf at least once every 6 months that the eligible IOTA waitlist beneficiary is on the IOTA participant's waitlist. For purposes of the model, CMS proposes to define "eligible IOTA waitlist beneficiaries" at §512.402 as IOTA waitlist patients, as defined at §512.402, who are Medicare beneficiaries and meet the following criteria:

- Are active on the IOTA participant's waitlist; and
- Have accrued a minimum of 3 years of waiting time on the IOTA participant's waitlist.

CMS seeks comment on its proposed definition of eligible IOTA waitlist beneficiaries at proposed §512.402.

[4] Hereafter, references to an IOTA waitlist patient means an IOTA waitlist patient who is a Medicare beneficiary.

CMS proposes that, beginning in PY 3, IOTA participants would be required to provide notification of declined organ offers for eligible IOTA waitlist beneficiaries who are on their waitlist every 6 months, starting July 1 of PY 3. This would be subject to the following conditions: (1) IOTA participants would only have to notify eligible IOTA waitlist beneficiaries with at least 3 years of accrued waiting time and (2) IOTA participants would have to provide this notification every 6 months after that time period. This proposed timeframe is designed to balance between the operational burden for IOTA participants and when eligible IOTA waitlist beneficiaries could start getting transplantation offers. To respect beneficiary choice, eligible IOTA waitlist beneficiaries would be able to opt out of this notification.

For each 6-month period in which an organ offer is received and declined, CMS proposes at §512.442(b)(1)(i)(A) through (F) that the IOTA participant must provide notifications to each eligible IOTA waitlist beneficiary, as defined at proposed §512.402, and include all of the following:

- How much wait-time the eligible IOTA waitlist beneficiary is currently listed with and their percent panel-reactive antibody (PRA) value.
- In each 6-month period, how many match-runs, as defined at §512.402, the eligible IOTA waitlist beneficiary came up on and how many donors they received kidney organ offers from.
- Unique patient-specific considerations for that eligible IOTA waitlist beneficiary for which deceased donor kidneys the IOTA participant would consider for that eligible IOTA waitlist beneficiary.
- The refusal reason(s) why offers were declined based off the OPTN refusal codes in plain language.
- Of the deceased donor kidney organ offers declined for that eligible IOTA waitlist beneficiary, how many of those kidneys were transplanted in another kidney transplant patient, as defined at §512.402.
- Potential avenues to accelerate access to transplant (for example, exploring living donation, being waitlisted at multiple kidney transplant hospitals, reviewing transplant organ offer acceptance criteria or ensuring they meet and maintain the patient criteria for their chosen kidney transplant hospital(s), such as adhering to weight loss recommendations).

CMS believes that these proposed requirements would best balance transparency for the eligible IOTA waitlist beneficiary and ensure the information is as useful as possible for them. Due to the many concerns that CMS received, CMS recognizes that monthly notification to Medicare beneficiaries regarding volume and reason for organ decline could have been very burdensome to IOTA participants and their staff in PY 1 since this was a new initiative and there were not current infrastructure or database resources to aid in minimizing burden on IOTA participants (89 FR 96397). CMS believes though that circumstances have changed relative to when it wrote the 2024 Final Rule for the following reasons: (1) the IOTA Model has already started; (2) the updated provisions that CMS is proposing are responsive to many of the administrative burden concerns that were previously raised by commenters; (3) CMS has been working with the Health Resources and Services Administration (HRSA) for operational assistance to help make sure that

this information is easily accessible for IOTA participants and in a format that could be easily shared with its eligible IOTA waitlist beneficiaries.

CMS states that it considered several alternatives to its proposed approach including the following:

- Requiring that an IOTA participant begin providing notification of declined organ offers 3 years from when a beneficiary started dialysis, but it did not propose that as CMS knows some beneficiaries get onto the waitlist before they start dialysis.
- Considered proposing 1 or 2 years of waitlist time, as well as 4 or 5 years, but it decided to propose 3 years as a way to balance when it would be appropriate for eligible IOTA waitlist beneficiaries to start being informed of their offers.
- Considered proposing other timeframes for potentially notifying eligible IOTA waitlist beneficiaries about kidney transplant organ offers including monthly, quarterly, or annually, but it proposed every 6 months to align with the model's review of acceptance criteria requirement at §512.442(c) and the proposed change in waitlist status requirement.
- Considered a variation of organ offer notifications, where every 6 months the IOTA participant would be required to also provide the total number of kidney transplant organ offers the IOTA participant received and accepted in the relevant 6-month period in addition to the kidney transplant organ offers for the individual eligible IOTA waitlist beneficiary.
- Considered limiting this proposed requirement exclusively to kidney transplant organ offers that were ultimately transplanted; however, CMS determined that the requirement to inform eligible IOTA waitlist beneficiaries of the disposition of each kidney transplant organ offer would accomplish the same objectives while providing more comprehensive information to the eligible IOTA waitlist beneficiary.
- Considered not requiring the sharing of offers further up in the match run, as defined at §512.402, at spot 100 or higher to align with the SRTR definition of hard-to-place organ or spot 150, but it wanted to err on the side of providing greater transparency to eligible IOTA waitlist beneficiaries.
- Considered excluding multi-organ offers from this provision; however, CMS did not propose such exclusion because it wanted to ensure that eligible IOTA waitlist beneficiaries would receive a more complete perspective regarding their care.
- Considered requiring other explanations for why each kidney transplant organ offer was declined, in order to provide additional specificity where appropriate, but it decided to propose OPTN refusal codes in order to provide a standardized approach for IOTA participants using a format they are already familiar with.
- Considered requiring cumulative information of organ offers declined since the eligible IOTA waitlist beneficiary was added to the IOTA participant's waitlist, but it was unsure if that would provide additional useful information for these beneficiaries.
- Considered but did not propose creating a standardized notification template for IOTA participants to use that would include the information specified at proposed §512.442(b)(1)(i)(A) through (F).

CMS also believes that requiring IOTA participants to use a CMS-provided standardized template for these notification requirements could be beneficial because it would ensure uniform

implementation across all IOTA participants, eliminating variability in how critical patient-specific information is communicated and significantly reducing the administrative burden on individual IOTA participants by providing ready-to-use formats rather than requiring each IOTA participant to develop custom systems. **While CMS is not proposing to provide a standardized notification template that IOTA participants would be required to use, CMS is seeking comment regarding whether the inclusion of such templates would be preferable and would not impose additional administrative burden upon IOTA participants. Additionally, beyond the proposed requirements, CMS seeks comment on what specific requirements or specific details should be included in or excluded from such a notification template.**

To communicate with the eligible IOTA waitlist beneficiary effectively, CMS proposes at §512.442(b)(2) that the IOTA participant must provide this notification via patient visit, email, electronically, or mail on an individual basis, unless the eligible IOTA waitlist beneficiary opts out of this notification. CMS proposes at §512.442(b)(2)(i) to require IOTA participants to give eligible IOTA waitlist beneficiaries the opportunity to opt out of receiving this notification. CMS proposes at §512.442(b)(2)(ii) that if an eligible IOTA waitlist beneficiary opts out of receiving this notification, the IOTA participant would be required to do the following:

- Record in the eligible IOTA waitlist beneficiary's medical record the following:
  - The date on which this notification was declined.
  - The method by which this notification was declined.
- Offer to provide this notification once every 6 months at which time the eligible IOTA waitlist beneficiary would have the opportunity to opt out of receiving this notification again.

CMS also proposes at §512.442(b)(3)(i) through (iii) that the IOTA participant must record in the eligible IOTA waitlist beneficiary's medical record that the beneficiary received the notification, the method the notification was delivered, and the date of delivery.

Additionally, CMS proposes at §512.442(b)(4) that the waitlist transparency information at proposed §512.442(b)(1) must be provided to the eligible IOTA waitlist beneficiary's nephrologist or nephrology professional, to provide the opportunity for questions and clarification of information.

CMS alternatively considered proposing that the IOTA participant must record in the eligible IOTA waitlist beneficiary's medical record—

- That the eligible IOTA waitlist beneficiary was sent the notification specified in proposed §512.442(b)(1);
- The method by which the notification was sent; and
- The date by which the notification was sent.

In this alternative, requiring IOTA participants to document when a notification was sent rather than when it was delivered recognizes the practical challenges of verifying receipt while still ensuring accountability. However, CMS chose not to propose this alternative because it believes recording only when a notification was sent does not confirm that the information reached the eligible IOTA waitlist beneficiary.

CMS seeks comment on its proposals to provide transparency into kidney transplant organ offers at proposed §512.442(b). CMS also seeks comment on the alternatives considered.

4. Review of Acceptance Criteria

As finalized in the 2024 Final Rule (89 FR 96402), IOTA participants will be required to review transplant organ offer acceptance criteria with their IOTA waitlist patients at least once every 6 months that the Medicare beneficiary is on their waitlist, unless the Medicare beneficiary opts out of this review. Under this provision, the IOTA participant must conduct this review via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review.

Since publication of the 2024 Final Rule, IOTA participants have requested that CMS provide clarification on what acceptance criteria information should be reviewed. Therefore, in this proposed rule, CMS aims to clarify at §512.442(c) that review of acceptance criteria pertains to individual patient transplant organ offer acceptance criteria and not organ offer filters or kidney transplant hospital level acceptance criteria. For purposes of the model, CMS proposes at §512.402 to define "transplant organ offer acceptance criteria" as individualized patient acceptance parameters that kidney waitlist patients, as defined at §512.402, may elect regarding the categories of organ offers they are prepared to accept for transplantation.

CMS seeks comment on its proposal to clarify the meaning of transplant organ offer acceptance criteria. CMS also seeks comment on the proposed definition for transplant organ offer acceptance criteria.

As described earlier in this section, in the 2024 Final Rule CMS finalized at §512.442(c)(1) that IOTA participants must conduct the review of acceptance criteria via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review. Since publication, CMS provided sub-regulatory guidance to IOTA participants in the IOTA Model Newsletter on how IOTA waitlist patients can opt out of this review. However, upon further review of the sub-regulatory guidance CMS provided to IOTA participants, CMS believes further guidance is needed.

As such, CMS proposes at §512.442(c)(1)(i) that prior to reviewing transplant organ offer acceptance criteria, as defined at proposed §512.402, with IOTA waitlist patients, IOTA participants must give these beneficiaries an opportunity to decline this review. Further, CMS proposes at §512.442(c)(1)(ii) that if the IOTA waitlist patient declines this review, the IOTA participant must record in the IOTA waitlist patient's medical record the following:

- The date on which this review was declined; and
- The method by which this review was declined.

CMS also proposes that if an IOTA waitlist patient declines this review, the IOTA participant would then be required to offer the IOTA waitlist patient the opportunity to review transplant organ offer acceptance criteria once every 6 months, at which time the IOTA waitlist patient would have the opportunity to decline this review again.

CMS seeks comment on these proposed requirements at proposed §512.442(c)(1)(i) and (ii).

Lastly, to facilitate compliance monitoring, CMS proposes at §512.442(c)(2)(i) through (iii) that the IOTA participant must record in the medical record of the IOTA waitlist patient all of the following:

- The information specified at §512.442(c) was reviewed with the IOTA waitlist patient who is a Medicare beneficiary;
- The date on which this review took place; and
- The method by which this review was delivered.

CMS seeks comment on these proposed documentation requirements at proposed §512.442(c)(2)(i) through (iii).

5. Change in Waitlist Status

Transplant hospitals are currently required to promptly notify patients awaiting transplantation of any program-related circumstances that could affect their ability to receive a transplant (see 42 CFR 482.102(c)). These regulations mandate that transplant hospitals must inform patients of factors such as the availability of transplant surgeons and changes in the hospital's operational status. Transplant hospitals must also notify patients of any modifications to their Medicare certification status, whether due to voluntary program inactivation or termination. These notification requirements serve as a crucial mechanism to ensure transparency and protect patient interests throughout the transplant waiting period.

Patients on the transplant waiting list are designated as either "active" or "inactive." Individuals with active status are prepared and eligible to be matched with available organs, whereas those with inactive status are not yet ready to, nor can they, receive organ offers. There are over 90,000 people on the waiting list for a kidney transplant, but nearly half (49 percent) of these individuals on the waiting list are listed as "inactive" as of 2025 and unable to receive a kidney transplant. While a transplant hospital is required to notify patients when they are first added to or removed from a waitlist, there is currently no requirement for transplant hospitals to inform patients on its waitlist when there is a change in waitlist status (that is, from active to inactive). It is important for transplant candidates to be aware of whether they are active or inactive on the waiting list and to understand that they are only eligible to receive an organ for transplant while in an active status.

To address this issue, CMS proposes to add new requirements at §512.442(d) for IOTA participants to notify their IOTA waitlist patients when their waitlist status has changed. Specifically, CMS proposes, at §512.442(d)(1)(i), that IOTA participants must notify their IOTA waitlist patients any time their status on its waitlist is changed and that change would impact their ability to receive an organ offer (that is, from active to inactive). Note that CMS is not proposing to require IOTA participants to notify IOTA waitlist patients when their status changes from inactive to active as CMS states this may impose significant administrative burden and could cause patient anxiety and unrealistic expectations about organ immediacy.

CMS further proposes at §512.442(d)(1)(ii) that IOTA participants must include all of the following in this notification to IOTA waitlist patients:

- The most recent date the IOTA waitlist patient became inactive.
- The reason for the change in waitlist status.
- That the IOTA waitlist patient cannot receive organ offers while inactive.
- Information on how the IOTA waitlist patient may become active on its waitlist again (for example, updating personal information, providing new clinical data, addressing insurance issues or other factors such as medical, psychosocial, and socioeconomic).
- How the IOTA waitlist patient may contact the IOTA participant for more information or with any questions.

CMS seeks comment on its proposed change in waitlist transparency requirement at proposed §512.442(d)(1)(i) and its waitlist status notification requirements at proposed §512.442(d)(1)(ii). CMS is also interested in comments on whether the proposed information to include in the change in waitlist status notification should include additional information.

CMS also proposes at §512.442(d)(1)(iii) that IOTA participants must provide this notification to the IOTA waitlist patient—

- Electronically or by mail;
- Within 10 days of the IOTA waitlist patient's change in waitlist status – consistent with the patient records requirements at §482.94(c)(2); and
- Annually, thereafter, for as long as the Medicare beneficiary remains inactive (that is; 365 consecutive days). This annual notice requirement for a Medicare beneficiary is triggered based on inactive status of 365 consecutive days rather than a specified timeline.

CMS considered a number of alternative methodologies for implementing this provision. For example, CMS considered delaying the implementation of this provision until PYs 3 or 4, in conjunction with the proposed transparency into kidney transplant organ offers requirement to share information about declined kidney transplant organ offers. CMS also considered alternative timelines for continued notification that an IOTA waitlist patient remains inactive on an IOTA participants waitlist, such as every 60 days, 90 days, or 180 days. Further, CMS considered alternatives based on inactive status for a specified period of time, when the Medicare beneficiary was ultimately discharged from a hospital, and informing IOTA waitlist patients about internal holds.

CMS seeks comment on its proposed change in waitlist status delivery method and timeline requirements at proposed §512.442(d)(1)(iii)). CMS also seeks comment on the alternatives considered.

CMS also proposes at §512.442(d)(2) that the IOTA participant must record in the medical record of the IOTA waitlist patient all of the following:

- A copy of the notification.
- The method by which the notification was delivered.
- The date of when the notification was delivered.

Additionally, CMS proposes at §512.442(d)(3) that for IOTA waitlist patients and –

- For ESRD patients, the IOTA participant must also notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at 42 CFR 512.310) or nephrologist; or
- For Non-ESRD patients, the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient.

This notification timeframe conforms with the current timeframe at §482.94; however, CMS seeks comment on alternative timeframes that may be appropriate. CMS seeks comment on documentation requirements at proposed §512.442(d)(2) through (3).

E. Health Equity Plans

In the 2024 Final Rule, CMS finalized that an IOTA participant may voluntarily submit a health equity plan (HEP) to CMS. CMS finalized voluntary health equity plan submissions aiming to address reducing health disparities for attributed patients. However, in an effort to align with priorities of this Administration and address concerns of added burdens on IOTA participants in a mandatory model, CMS is proposing to remove the voluntary health equity plan submissions and to remove all health equity plan provisions and related definitions from the IOTA Model. CMS states that this proposed policy change would enable IOTA participants to focus limited resources on care redesign activities that would improve their model performance and the quality of care and experience for the attributed patient. While CMS is not currently proposing a replacement for these policies, CMS may consider incorporating elements that align with the current Administration's focus on Making America Healthy Again (MAHA)policies in future years through notice and comment rulemaking.

CMS seeks comment on its proposal to remove health equity plans from the IOTA Model and remove the corresponding regulations at §512.446. CMS also seeks comment on its proposal at §512.402 to remove the definitions of health equity goals, health equity plan intervention, health equity plan performance measure(s), health equity project plan, resource gap analysis, target health disparities, and underserved communities.

F. Beneficiary Protections

CMS finalized in the 2024 Final Rule that IOTA participants must provide notice to each attributed patient of its participation in the IOTA Model. CMS is proposing updates to this provision that would include the following modifications:

- Limit these notification requirements to Medicare beneficiaries only.
- Allow IOTA participants to distribute this notification in a paper notification at the first in-office or outpatient visit, or to distribute the notification in an electronic format in cases where the attributed patient has affirmatively opted out of receiving paper communications.

CMS seeks comment on its proposal at proposed §512.450(a)(3)(iii)(A) and (B) to allow IOTA participants to distribute this paper notification at the first in-office or outpatient visit, or to distribute the notification in an electronic format in cases where the attributed patient has affirmatively opted out of receiving paper communications.

G. Monitoring

In the 2024 Final Rule, CMS finalized a comprehensive list of monitoring activities to ensure compliance and promote the safety of attributed patients and the integrity of the IOTA Model. However, CMS inadvertently omitted monitoring of the review of acceptance criteria provision as described in §512.442. Therefore, in this proposed rule CMS is proposing monitoring of the following transparency provisions:

- Publicly posting selection criteria in accordance with §512.442(a);
- Informing eligible IOTA waitlist patients, as defined in section II.B.4.a.(3). of this proposed rule, of the number of times an organ is declined on the Medicare beneficiary's behalf in accordance with proposed §512.442(b);
- Reviewing selection criteria with IOTA waitlist patients at least once every 6 months that the Medicare beneficiary is on their waitlist as specified in §512.442(c); and
- Notifying IOTA waitlist patients when their waitlist status has changed from active to inactive in accordance with proposed §512.442(d).

CMS proposes at §512.462(b)(2)(xi), (xii), (xiii) and (xiv) to include that CMS may monitor the review of acceptance criteria provision in accordance with §512.442. **CMS seeks comment on these proposed requirements.**

H. Remedial Action and Termination.

In the 2024 Final Rule, CMS finalized a comprehensive list of reasons for which CMS may immediately or with advance notice terminate an IOTA participant from the IOTA Model. CMS inadvertently omitted the Department of Health and Human Services (HHS) and the Organ Procurement and Transplantation Network (OPTN) as sources of vital information regarding potential events by IOTA participants identified as presenting a risk to patient safety, public health, and related concerns that may lead CMS to terminate IOTA participants. Therefore, in this proposed rule CMS is proposing to include that CMS may terminate an IOTA participant from the IOTA Model if HHS or the OPTN has determined that an IOTA participant has violated the OPTN's policies, OPTN's Management and Membership policies, or the HHS's regulation on OPTN (42 CFR 121) upon a review conducted pursuant to 42 CFR 121.10, along with minor technical corrections to accommodate this proposal.

CMS seeks comment on its proposal at proposed §512.466(a)(3)(ix)(C) to include OPTN as a source of information that may lead to CMS terminating an IOTA participant from the IOTA Model. CMS also seeks comment on its minor technical corrections at proposed §512.466(a)(3)(ix)(A) and (B).

I. Requests for Information (RFIs) on Topics Relevant to the IOTA Model

This section includes two requests for information (RFIs). In responding to the RFIs, the public is encouraged to provide complete, but concise responses. CMS states that it will not respond to questions about the policy issues raised in these RFIs.

1. Pre-transplantation Access Process Measure

In the 2024 Final Rule (89 FR 96346), CMS discussed that before a patient can be considered for, and placed on, the waiting list for a kidney transplant, they must first be referred by either a nephrologist or dialysis facility, at which point they undergo a comprehensive evaluation process by a transplant hospital. In the United States, kidney transplant waitlist candidates face considerable disparities in access to kidney transplants, such as in who is referred and placed on the waiting list, who remains "active" on the waiting list, and how waitlisted patients are managed by kidney transplant hospitals.[5]

While waitlisting metrics could effectively measure the total organ need at each transplant hospital and reduce dependency on regional organ availability, no standardized metrics currently exist to compare waitlisting rates between transplant programs. CMS states that including pre-transplant process measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making. 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 is seeking comments on the following questions and encourages commenters to provide empirical evidence to support their feedback whenever possible:

- *For Kidney Transplant Hospitals*: What existing measures are being used to measure access to the waitlist or transplantation evaluation processes?
    - What are the domains, strengths, and weaknesses of these measures?
    - Are there factors that could make these measures more meaningful and practical?
    - Are there existing measures being used to measure time from referral to waitlist or waitlist to transplantation?
    - Would this type of measurement be useful for improving access to kidney transplantation?
    - How do these measures provide information that can be used to improve patient care and healthcare systems?
    - What unintended consequences could arise by measuring waitlist to referral and pre-transplant processes?
    - What data would be necessary to create measures of time from referral to waitlist and time from waitlist to transplant?
    - How could that data be transmitted to CMS in a way that minimizes burden to transplant hospitals?
    - What data would be necessary to create a measure on those specified components?

- *For Kidney Transplant Recipients and Dialysis and ESRD Patients*: Why is a quality measure that looks at access to waitlist and pre-transplantation processes important to

[5] Whelan, A. M., Johansen, K. L., Copeland, T., McCulloch, C. E., Nallapothula, D., Lee, B. K., Roll, G. R., Weir, M. R., Adey, D. B., & Ku, E. (2022). Kidney transplant candidacy evaluation and waitlisting practices in the United States and their association with access to transplantation. American Journal of Transplantation, 22(6), 1624–1636. https://doi.org/10.1111/ajt.17031.

include?
    - What criteria would make this type of measure most useful for driving access to kidney transplantation?

- *For All Stakeholders*: When measuring pre-transplantation processes, what specific components should be analyzed (for example, time from referral to waitlist, time from waitlist to transplant)?

2. Allocation Out-of-sequence (AOOS)

In the 2024 Final Rule (89 FR 96429), CMS discussed its concerns around the issue of AOOS transplants. Specifically, CMS is concerned about IOTA participants bypassing the match run, or the OPTN policy-defined rank order list of transplant candidates to be offered an organ. This practice may undermine the mechanisms promoting equitable allocation in rationing this scarce resource. CMS finalized a provision at §512.462(b)(2)(x) which states that monitoring activities may include monitoring AOOS of kidneys by assessing the frequency at which IOTA waitlist patients, top-ranked on an IOTA participant's kidney transplant waitlist, receive the organ that was initially offered to them; and determining the reasons behind cases where IOTA waitlist patients did not receive the kidney offered to them. CMS is working on implementing this provision as part of its monitoring efforts for the model.

Under the oversight of HRSA, the OPTN establishes allocation policies and is charged with investigating incidences of organs being allocated out of the OPTN-defined sequence. On August 30, 2024, HRSA provided a critical comment letter to the OPTN and OPTN contractor related to a complaint on this issue.[6] In that letter, HRSA pointed out the OPTN bylaws requiring that each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. In June 2025, HRSA launched a dedicated AOOS web page to serve as a centralized resource, offering background on AOOS, ongoing updates, and opportunities for stakeholders and the public to submit questions and provide input.

In response to the 2024 Proposed Rule, CMS received numerous comments from the public worried about the impact of the IOTA Model on further promoting AOOS. While CMS did not make any changes in the 2024 Final Rule based on these comments, AOOS remains an issue of concern for CMS and HRSA. **As a result, CMS seeks comments from all stakeholders on the following questions**:

- 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?
- 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?
- What de-identified data would be helpful for CMS and HRSA to share with the public about the use of AOOS in the IOTA Model and in the overall transplant system?
- 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

[6] Critical Comment Redacted Letter to OPTN - 08302024

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?

- Through its monitoring efforts laid out in §512.462(b)(2)(x), CMS plans to monitor AOOS. What considerations or stratifications should CMS take into account when monitoring AOOS?

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III. Regulatory Impact Analysis

The IOTA Model aims to incentivize transplant hospitals to overcome system-level barriers to kidney transplantation. The chronic shortfall in kidney transplants results in poorer outcomes for patients and increases the burden on Medicare in terms of payments for dialysis and dialysis-based enrollment in the program. CMS provides a detailed analysis of the impacts that the proposed changes would have on affected IOTA participants and beneficiaries.

In Table 8 in the proposed rule (reproduced below), CMS show the net impact of the proposed changes on projected model outcomes (proposed impacts less the revised baseline impacts). The increase in model spending related to the revisions to the incentive methodology are projected, on average, to result in marginally greater overall savings through additional growth in transplantation. The model's net impact is projected to save nearly $20 million more in total over 6 years relative to the revised baseline.

Table 8: Projected Impact of Proposed Rule Changes: Proposed Model Less Revised Baseline

							6-Year Totals		
	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28	7/1/28-6/30/29	7/1/29-6/30/30	7/1/30-6/30/31	Mean	10th Percentile	90th Percentile
Upside Risk Payments	-4	-4	-4	-4	-6	-6	-28		
Downside Risk Payments	0	0	0	0	0	0	-2		
Total Net Payments	-4	-4	-4	-5	-6	-6	-30		
Added Transplants	-11	-24	-39	-56	-70	-73	-273		
Impact on Federal Spending	0	1	1	2	2	3	9		
Mean Net Savings	-3	-4	-3	-3	-4	-3	-21	-13	-29

While the model is focused on transplant outcome measures that would be calculated by CMS, there would likely be some additional burden for compliance for the IOTA participants. Total estimated hospital cost per year is $9,519. CMS estimates that the total cost would come out to $980,457.00 to complete the review of organ offer acceptance criteria for the 103 kidney transplant hospitals selected as IOTA participants.

CMS considered an alternative policy that would both (a) include Medicare Advantage (MA) enrollees in the definition of Medicare kidney transplant recipients so that upside risk payments and downside risk payments are based on kidney transplants for beneficiaries with Medicare FFS or MA as a primary or secondary payer, and (b) reduce the maximum incentive payment from $15,000 to $10,000 per transplant.

In Table 11 in the proposed rule (recreated below), CMS shows the net impact of the proposed changes on projected model outcomes for this alternative (proposed impacts less the revised baseline impacts). Despite including MA transplants in this alternative policy, overall incentive payments would still decline marginally because of other changes to the methodology and a reduction in the maximum incentive amount to $10,000. However, total new transplants are anticipated to grow marginally because of a broader and more uniform deployment of the incentive over the overall Medicare population. Net savings are also marginally improved by the marginal added savings per transplant assumed for MA transplants. Under the alternative policy, the model's net impact would have been projected to save nearly $70 million more in total over 6 years relative to the revised baseline (a $48 million greater increase than the proposed policy is estimated to produce in Table 8).

Table 11: Projected Impact of Proposed Rule Changes: Alternative Policy Less Revised Baseline									
							6-Year Totals		
	7/1/25-6/30/26	**7/1/26-6/30/27**	**7/1/27-6/30/28**	**7/1/28-6/30/29**	**7/1/29-6/30/30**	**7/1/30-6/30/31**	**Mean**	**10th Percentile**	**90th Percentile**
Upside Risk Payments	-3	-4	-4	-4	-5	-5	-25		
Downside Risk Payments	0	-1	-1	-1	-1	-1	-3		
Total Net Payments	-3	-4	-4	-5	-6	-6	-28		
Added Transplants	16	34	55	78	91	96	371		
Impact on Federal Spending	-2	-3	-6	-8	-10	-11	-40		
Mean Net Savings	-5	-8	-10	-13	-16	-17	-69	-89	-54