DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5544–P]

RIN 0938–AV65

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the Increasing Organ Transplant Access (IOTA) Model for Performance Year (PY) 2.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by February 9, 2026.

ADDRESSES: In commenting, please refer to file code CMS–5544–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5544–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5544–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

CMMItransplant@cms.hhs.gov, for questions related to the Increasing Organ Transplant Access Model.

Thomas Duvall, (410) 786–8887, for questions related to the Increasing Organ Transplant Access Model.

Christina McCormick, (410) 786–4012, for questions related to the Increasing Organ Transplant Access Model.

Lina Gebremariam, (410) 786–8893, for questions related to the Increasing Organ Transplant Access Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This proposed rule would make changes to the Increasing Organ Transplant Access (IOTA) Model for Performance Year (PY) 2, which will begin on July 1, 2026, and future PYs.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. A general summary of the changes in this proposed rule is presented in section II.B of the preamble of this proposed rule.

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, 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 each of the baseline years. However, 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. Therefore, we are proposing 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, as described in section II.B.1.b. of this proposed rule.

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, 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 our experience in operating the model, we believe it is necessary to reevaluate the low volume threshold requiring a kidney transplant hospital to have performed at least 11 kidney transplants annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model. As such, as described in section II.B.1.b. of this proposed rule, we are proposing 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.

b. Performance Assessment

In the 2024 Final Rule, we 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, we 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, we would go through rulemaking in the future to promulgate new or updated policies that would be finalized after the model start date. Therefore, as described in section II.B.2.b.(2).(a). of this proposed rule, we are proposing updates to the composite

graft survival rate metric that would include the following modifications:

- Adding a risk-adjustment methodology that includes several transplant recipient and donor characteristics (for example, transplant recipient and donor age, diabetes status, sex, kidney function (eGFR/creatinine).
- Excluding multi-organ transplants from the composite graft survival rate exclusion and inclusion criteria, in recognition of their more complicated results for kidney transplant recipients.
- Updating the allocation of points awarded for performance on the composite graft survival rate.

A detailed description of each proposed policy change and the corresponding scoring criteria can be found in section II.B.2.b. of this proposed rule.

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.

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. As described in section II.B.3.c.(2). of this proposed rule, 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. As proposed in section II.B.3.c.(2). of this proposed rule, 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.

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. As described in section II.B.3.c.(3). of this proposed rule, 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 updates to the EUC provisions that would 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 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.

d. Other Requirements

In the 2024 Final Rule, CMS finalized several other model requirements for IOTA participants, including transparency requirements, public reporting requirements, and a health equity plan requirement which is optional for the IOTA Model performance period. In the 2024 Final Rule, CMS signaled that there were several policies that would be updated through future rulemaking. In addition, there were several policy considerations raised subsequent to the publication of the 2024 Proposed Rule, including through public comment, which CMS would like to incorporate into the IOTA Model, but were unable to add to the 2024 Final Rule. Therefore, this proposed rule proposes updates to other requirements in the IOTA Model.

a. Transparency

In the 2024 Final Rule CMS finalized that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1. CMS also stated its intent to use future rulemaking to determine the cadence of updating this website and patient selection criteria. As such, this proposed rule proposes updates to this requirement that includes the following modifications:

- For all subsequent PYs after PY1, the IOTA participant must review its publicly posted patient selection waitlist criteria and ensure that the information on its website is up to date by the end of each relevant PY.
- IOTA participants performing living donor transplants must publicly post their living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients by the end of PY 2. IOTA participants must ensure the accuracy of this information by the end of each subsequent PY.

Each of the proposed provisions is discussed in detail in section II.B.4.a.(1). of this proposed rule.

CMS also finalized its intent in the 2024 Final Rule to identify each IOTA participant for each PY and to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant on the IOTA Model website annually, as they become available. As proposed in section II.B.4.a.(2). of this proposed rule, we are proposing to publish IOTA participant waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this proposed rule, on the IOTA Model website by the end of the second quarter of each subsequent PY.

As discussed in the 2024 Final Rule, 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. A

provider may decline an organ offer for any number of reasons; however, declining without disclosing the rationale with the patient may miss an important opportunity for shared decision-making. As described in the 2024 Final Rule, CMS proposed monthly transparency requirements for IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries about declined organ offers and the reasons for declination. However, following feedback from 2024 Proposed Rule public comments that this policy would impose a significant administrative burden on IOTA participants, CMS decided not to finalize this transparency requirement and instead committed to consider alternatives, such as alternative frequencies for sharing declined organ offers with Medicare beneficiaries, while remaining invested in evaluating alternative transparency opportunities for patients on the waiting list with the transplant community to fulfill this important need. In this proposed rule, we are proposing an alternative approach for the model, as described in section II.B.4.a.(3). of this proposed rule. As proposed in section II.B.4.a.(3). of this proposed rule, beginning in PY 3, IOTA participants must provide semi-annual (that is, at least once every 6 months) notifications to ''eligible IOTA waitlist beneficiaries,'' as defined in section II.B.4.a.(3). of this proposed rule, detailing the number and reasons for organ declinations made on their behalf, with eligible IOTA waitlist beneficiaries retaining the right to opt out of receiving these notifications.

In the 2024 Final Rule, CMS finalized a requirement that IOTA participants must review organ offer acceptance criteria with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. IOTA participants have since requested that CMS provide clarification on what acceptance criteria information should be reviewed. Therefore, as described in section II.B.4.(a).(4). of this proposed rule, we aim to clarify 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, we are also proposing 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.

Lastly, CMS is proposing the adoption of the following provisions for IOTA participants to notify its IOTA waitlist patients who are Medicare beneficiaries when their waitlist status has changed (that is, from active to inactive) only if it is not redundant with other HHS guidance: If finalized, the IOTA participant would be required to: (1) inform IOTA waitlist patients who are Medicare beneficiaries any time their status on its waitlist is changed that would impact their ability to receive an organ offer; (2) include the reason, and information about how IOTA waitlist patients who are Medicare beneficiaries could become active again; and, (3) notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at *42 CFR 512.310*) or nephrologist if applicable. IOTA participants would be required to notify these IOTA waitlist patients who are Medicare beneficiaries of status changes within 10 days when they become ineligible for organ offers (if not redundant with existing HHS guidance). This proposed provision is discussed in detail in section II.B.4.a.(5). of this proposed rule.

b. 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 the Administration and address concerns of added burdens on IOTA participants in a mandatory model, we decided to remove the voluntary health equity plan submissions and are proposing to remove all health equity plan provisions and related definitions from the IOTA Model as described in section II.B.4.b. of this proposed rule. 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) in future years through notice and comment rulemaking.

e. 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. As described in section II.B.5. of this proposed rule, we are 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.

f. Monitoring

In the 2024 Final Rule, we 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, we inadvertently omitted monitoring of the review of acceptance criteria provision as described in § 512.442. Therefore, in this proposed rule we are proposing to include that CMS may monitor the following transparency provisions as described in section II.B.6 of this proposed rule:

- Informing eligible IOTA waitlist patients who are Medicare beneficiaries, 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 who are Medicare beneficiaries 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 who are Medicare beneficiaries when their waitlist status has changed from active to inactive in accordance with proposed § 512.442(d).

g. Remedial Action and Termination

In the 2024 Final Rule, we finalized a comprehensive list of reasons for which CMS may immediately or with advance notice terminate an IOTA participant from the IOTA Model. As mentioned in section II.B.7. of this proposed rule, we 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 we are 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 (42 CFR 121) upon a review conducted pursuant to *42 CFR 121.10,* along with minor technical corrections to accommodate this proposal as described in section II.B.7 of this proposed rule.

h. Request for Information (RFI) on Topics Relevant to IOTA Model

As part of the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule (2024 Proposed Rule) published in the **Federal Register** in May 2024 (89 FR 43518), we stated that our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume.[1] We are seeking public input and comments on a future access to waitlist quality process measure to be specified, tested, and implemented for future years of the IOTA Model, titled ''Pre-transplantation Access Process Measure''.

In the 2024 Final Rule, CMS finalized monitoring allocation out-of-sequence (AOOS) kidneys as a monitoring activity. In response to the 2024 Proposed Rule, we received numerous comments from the public worried about the impact of the IOTA Model on further promoting AOOS. Additionally, on August 30, 2024, HRSA provided a critical comment letter to the OPTN and OPTN contractor regarding a complaint that they received, in which HRSA emphasized the OPTN policies requiring each OPO to maintain a plan for equitable organ allocation among transplant patients consistent with OPTN obligations. While we did not make any changes in the 2024 Final Rule based on the comments received, AOOS remains an issue of concern for CMS and HRSA. As such, in this proposed rule, we would like to seek public comments on potential policies CMS could consider to address AOOS as part of the IOTA Model or through separate regulatory efforts.

3. Summary of Costs and Benefits

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. In section V of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected IOTA participants and beneficiaries. We estimate that as a result of the proposed changes to the IOTA Model, net Federal savings would increase by $21 million.

B. Model Overview and Background

The Increasing Organ Transplant Access (IOTA) Model is a 6-year mandatory alternative payment model tested by the CMS Innovation Center under section 1115A of the Social Security Act (the Act) that began on July 1, 2025, and will end on June 30, 2031. The model appeared in the December 4, 2024 **Federal Register** (*89 FR 96280*) titled ''Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model'' (hereinafter referred to as the 2024 Final Rule), and this proposed rule would update IOTA Model provisions in response to improvement opportunities that arose during implementation and to better align the model with new administration priorities. The IOTA Model is aimed at kidney transplant hospitals with the goal of increasing the number of kidney transplants, improving quality, and improving patient experience during the transplant process.

II. Proposed Changes to the Increasing Organ Transplant Access (IOTA) Model

A. Background

1. Purpose

The Increasing Organ Transplant Access (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 a monthly transparency requirement for IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries about declined organ offers and the reasons for declination. In addition, there were a number of policy considerations raised subsequent to the publication of the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule (2024 Proposed Rule), including through public comment, which CMS would like to incorporate into the IOTA Model, but were unable to add to the 2024 Final Rule. Therefore, this proposed rule proposes updates to the IOTA Model. The policies delineated in this proposed rule reflect our commitment to ensuring that the IOTA Model's incentive structure enhances the care delivery capabilities and efficiency of kidney transplant hospitals selected for participation, with the goal of improving quality of care while reducing program spending.

2. Statutory Authority and Background

Section 1115A of the Act authorizes the Center for Medicare and Medicaid Innovation (the ''Innovation Center'') to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures, while preserving or enhancing the quality of care furnished to such programs' beneficiaries. We have designed and tested both voluntary Innovation Center models—governed by participation agreements, cooperative agreements, and model-specific addenda to existing contracts with CMS—and mandatory Innovation Center models that are governed by regulations. Each voluntary and mandatory model features its own specific payment methodology, quality metrics, and certain other applicable policies, but each model also features numerous provisions of a similar or identical nature, including provisions

[1] We note that the definition and criteria for ''acceptable'' post-transplant outcomes has not been defined and, as stated in section II.B.2.b(2) of this proposed rule, we are seeking comment on how to define an acceptable level (for example, 1 standard deviation of the national risk-adjusted rate or some other way).

regarding cooperation in model evaluation; monitoring and compliance; and beneficiary protections.

Under the authority of section 1115A of the Act, through notice-and-comment rulemaking, the CMS Innovation Center established the IOTA Model in the 2024 Final Rule that appeared in December 4, 2024, **Federal Register** (*89 FR 96280*). The intent of the IOTA Model is to reduce Medicare expenditures and improve performance in kidney transplantation by creating performance-based incentive payments for participating kidney transplant hospitals tied to access and quality of care for ESRD patients on the hospitals' waitlists.

Participation in the IOTA Model is mandatory for approximately 50 percent of all eligible kidney transplant hospitals in the United States, which were selected by a stratified random sampling of donation service areas (''DSAs''). Mandatory participation in the IOTA Model was determined to be necessary to minimize the potential for selection bias and to ensure a representative sample size nationally, thereby guaranteeing that there would be adequate data to evaluate the model test. Eligible kidney transplant hospitals included those that: (1) performed at least 11 kidney transplants for patients 18 years of age or older annually regardless of payer type during the 3-year period ending 12 months before the model's start date; and (2) furnished more than 50 percent of the hospital's annual kidney transplants to patients 18 years of age or older during that same period. As this is a mandatory model, the selected kidney transplant hospitals are required to participate.

CMS measures and assesses IOTA participant performance during each PY across three performance domains: achievement, efficiency, and quality. The achievement domain assesses each IOTA participant on the number of kidney transplants performed during a PY, relative to a participant-specific transplant target. The efficiency domain assesses the performance of IOTA participants on the organ offer acceptance rate ratio relative to national ranking. The quality domain is focused on improving the quality of care and measures IOTA participants performance on the composite graft survival rate relative to national ranking to assess post-transplant outcomes. Each IOTA participant's performance score across these three domains determines its final performance score and corresponding amount for the performance-based incentive payment that CMS will pay to or the payment that will be owed by the IOTA participant. The upside risk payment will be a lump sum payment paid by CMS after the end of a PY to an IOTA participant with a final performance score of 60 or greater. Conversely, beginning PY 2, the downside risk payment will be a lump sum payment paid to CMS by any IOTA participant with a final performance score of 40 or lower. There is no downside risk payment for PY 1 of the IOTA Model.

B. Provisions of the Proposed Regulation

1. IOTA Participants

a. Background

In the 2024 Final Rule (*89 FR 96304*), we defined ''IOTA participant'' as a kidney transplant hospital, as defined at *§ 512.402,* that is required to participate in the IOTA Model pursuant to § 512.412. In addition, we noted that the definition of ''model participant'' contained in *42 CFR 512.110,* would include an IOTA participant. We also proposed and finalized at *§ 512.402* the definition of ''transplant hospital,'' ''kidney transplant hospital,'' and ''kidney transplant.'' We stated that kidney transplant hospitals are the focus of the IOTA Model because they are the entities that furnish kidney transplants to ESRD patients on the waiting list and ultimately decide to accept donor recipients as transplant candidates (*89 FR 96303*). Kidney transplant hospitals play a key role in managing transplant waitlists and patient, family, and caregiver readiness. They are also responsible for the coordination and planning of kidney transplantation with the organ procurement organizations (OPO) and donor facilities, staffing and preparation for kidney transplantation, and oversight of post-transplant patient care, and they are largely responsible for managing the living donation process. The IOTA Model is intended to promote improvement activities across selected kidney transplant hospitals that reduce access barriers, thereby increasing the number of transplants, quality of care, and cost-effective treatment. The IOTA Model aims to improve quality of care for ESRD patients on the waiting list pre-transplant, during transplant, and during post-transplant care.

b. Mandatory Participation

In the 2024 Final Rule (*89 FR 96308*), we finalized that participation in the IOTA Model would be mandatory. We proposed and finalized that all kidney transplant hospitals that meet the eligibility requirements at § 512.412(a), and that are selected through the participation selection process at § *512.412(b)* and *(c)* would be required to participate in the IOTA Model. Lastly, we also finalized our provisions for participant eligibility criteria for kidney transplant hospitals at § 512.412(a) for all eligible kidney transplant hospitals selected for participation in the model.

As stated in the 2024 Final Rule (*89 FR 96308*), we proposed kidney transplant hospital participant eligibility criteria that would increase the likelihood that: (1) individual kidney transplant hospitals selected as IOTA participants represent a diverse array of capabilities across the performance domains; and (2) the results of the model test would be statistically valid, reliable, and generalizable to kidney transplant hospitals nationwide should the model test be successful and considered for expansion under section 1115A(c) of the Act.

We proposed and finalized our participant eligibility criteria for kidney transplant hospitals at *§ 512.412(a)* in the 2024 Final Rule (*89 FR 96311*). Specifically, that eligible kidney transplant hospitals are those that: (1) performed 11 or more transplants for patients aged 18 years or older annually, regardless of payer type, each of the baseline years and (2) furnished more than 50 percent of its kidney transplants annually to patients over the age of 18 during each of the baseline years. We also finalized the definition of ''non-pediatric facility'' and ''baseline years'' at *§ 512.402.*

In the 2024 Final Rule, we finalized at § 512.412(a)(1) a low volume threshold requiring a kidney transplant hospital 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.

In our initial proposal in the 2024 Proposed Rule, we stated that we alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the 3 baseline years (89 FR 43541). However, we found that many kidney transplant hospitals consistently perform between 11 and 50 transplants per year. We received several comments expressing concern with the proposed low-volume kidney transplant threshold for IOTA participants. As described in the 2024 Final Rule at *89 FR 96309*, a commenter noted that there may be some unforeseen or unintended consequences of advantaging programs classified as ''low volume,'' where the volume is close to the dividing line, and vice versa. Additional commenters shared concerns that the low volume threshold of 11 kidney transplants performed will

disadvantage kidney transplant hospitals that furnish a smaller number of kidney transplants, as these transplant programs do not meet the requirements for Center of Excellence (COE) programs and have limited contracts with payers, and the low volume threshold does not ensure statistical significance. Several commenters recommended that CMS should increase the low volume threshold, setting the number of kidney transplants at a value such as 25, 50, or 100, to ensure statistical significance and avoid burden on kidney transplant hospitals that furnish a smaller number of kidney transplants. Finally, a commenter suggested CMS should only use the number of Medicare kidney transplants to determine eligibility, rather than 11 kidney transplants across all payers. Additionally, as described at *89 FR 96308* a commenter expressed concerns about the impact of the IOTA Model on small kidney transplant hospitals if participation was made mandatory. The commenter suggested that a low volume threshold of 100 kidney transplants, regardless of payer type, would be more appropriate. This, the commenter believed, would ensure small kidney transplant hospitals were excluded and protect access to kidney transplants in less populated areas.

In the 2024 Final Rule, we stated that the low volume threshold was designed to protect the confidentiality of Medicare and Medicaid beneficiaries and that this low volume threshold aligns with the minimum standards for CMS data display, preventing the release of information that could identify individual beneficiaries while ensuring statistical significance (*89 FR 96309*). Additionally, we stated that we excluded these low-volume kidney transplant hospitals that may lack the capacity to comply with the model's policies.

Since publication of the 2024 Final Rule, some IOTA participants close to the current low volume threshold have expressed concern about their ability to participate in the model and we believe it is necessary to reevaluate the low volume threshold requiring a kidney transplant hospital to have performed 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model. We also received multiple comments from the 2024 Proposed Rule urging us to increase the low volume threshold. As such, in this proposed rule, we are proposing at § 512.412(a)(1) to raise this 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. We are also proposing this provision in response to our experience in operating the model. IOTA participants who are above the current minimum threshold of 11 kidney transplants performed annually, but below the updated proposed threshold of a minimum of 15 kidney transplants performed annually are still quite small and have indicated structural difficulties in achieving the goals of the model and complying with the requirements of the model. This updated low volume threshold is designed to balance accommodating the needs of smaller kidney transplant hospitals to ensure that their transplant programs can remain viable and continue to serve their communities, while also trying to ensure a sufficient volume of kidney transplant hospitals to be able to test the model.

We 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, but think that a 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 power to be able to test the model. This proposed updated low volume threshold 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.

We seek comment on our proposal to adjust the low volume threshold at § 512.412(a)(1) to require that to be eligible for model participation, a kidney transplant hospital must have performed a minimum of 15 kidney transplants to patients aged 18 years or older annually, regardless of payer, each of the baseline years, rather than a minimum of 11 kidney transplants. We also seek public comment on the alternatives considered.

Additionally, since publication of the 2024 Final Rule, CMS has completed IOTA participant selection and notified IOTA participants of their selection to participate in the IOTA Model. Upon completion of selecting IOTA participants for inclusion in the model, we realized that an unintended consequence of the current participant eligibility criteria at *§ 512.412(a)* is that Department of Veterans Affairs (VA) medical facilities or military medical hospitals, also known as military medical treatment facilities (MTFs) could be selected to participate even though Medicare does not provide reimbursement for VA medical facilities or MTFs. A total of 103 kidney transplant hospitals were selected to participate in the model, including four VA medical facilities and one MTF.

Per *42 CFR 411.6(a)*, Medicare does not pay for services rendered by Federal providers of services or other Federal agencies. Additionally, Medicare does not provide payment for services that receive direct or indirect funding from a governmental entity (see *42 CFR 411.8*). As such we propose to update the participant eligibility criteria at *§ 512.412(a).* Specifically, we are proposing 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. We propose at § 512.402 to define a ''VA medical facility'' as defined 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, we propose 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.

Given that Medicare does not provide coverage for services furnished by a federal provider, federal agency, or any other government entity, whether the services are paid for directly or indirectly by a government source, we believe that VA medical facilities and MTFs should not be eligible to participate in the IOTA Model. Additionally, we do not believe that our proposal to exclude kidney transplant hospitals that are also a VA medical hospital or MTF from being eligible to participate in the IOTA Model would negatively affect the remaining IOTA participants or impact the IOTA Model nor CMS's ability to evaluate the model. Moreover, the model's evaluation would benefit from an analysis that only focuses on Medicare-participating kidney transplant hospitals. Since the fundamental purpose of the IOTA Model is to test interventions specifically within the Medicare system to improve quality of care and reduce

Medicare expenditures, including non-Medicare participating facilities like VA medical facilities and MTFs would introduce confounding variables that could obscure the model's true effectiveness. VA medical facilities and MTFs operate under entirely different payment structures, regulatory frameworks, and patient populations compared to Medicare-participating hospitals, making direct performance comparisons inappropriate and potentially misleading.

By excluding these facilities, the model evaluation can focus on a group of hospitals that all operate under similar Medicare reimbursement conditions, face comparable regulatory requirements, and serve similar patient populations, thereby providing more accurate data on whether the model's performance-based payment incentives actually drive improvements in transplant outcomes and cost efficiency within the Medicare system. This approach would also eliminate the analytical complexity of trying to account for the vastly different operational contexts between Medicare-participating kidney transplant hospitals and federal facilities, ultimately yielding more actionable insights for potential broader implementation of the IOTA Model across the Medicare program.

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

Lastly, to account for our proposed kidney transplant hospital participant eligibility criteria modifications at proposed § 512.412(a)(1) and (3), we propose updating the language at § 512.412(a). Specifically, we propose replacing ''meets both'' with ''meets all'' to specify that a kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in proposed § 512.412(b)(3), if the kidney transplant hospital meets all of the eligibility criteria at § 512.412(a).

We seek comment on our proposal at proposed § 512.412(a) to update existing language to account for our proposals at proposed § 512.412(a)(1) and (3).

2. Performance Assessment

a. Method and Scoring Overview

In the 2024 Final Rule (*89 FR 96326*), we finalized provisions to assess IOTA participants in the achievement domain, efficiency domain and quality domain and performance scoring approach at *§ 512.422(a).* We also finalized at § 512.402 the definition of ''final performance score'' as the aggregate sum of scores earned by the IOTA participant across all three domains for a designated PY.

b. Quality Domain

(1) Background

In the 2024 Final Rule (*89 FR 96358*), we finalized at *§ 512.402* the definition of ''quality domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure focused on improving the quality of transplant care as described in *§ 512.428.* We also finalized general provisions for the quality domain at *§ 512.424(a).*

We stated at *89 FR 96358,* that our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume.[2] We continue to believe that transplant hospital accountability for patient-centricity and clinical outcomes continues post-transplantation. While transplant outcomes have historically received the most attention, often at the exclusion of other factors, we sought to encourage a better balance in the system to offer the benefits of transplant to more patients.

(2) Post Transplant Outcomes

In the 2024 Final Rule (*89 FR 96361*), we finalized at *§ 512.428(b)(1)* a provision to assess IOTA participant performance each PY on post-transplant outcomes using the composite graft survival rate. We also proposed and finalized at *§ 512.402* the definition of composite graft survival rate (*89 FR 96361*).

(a) Calculation of Metric

In the 2024 Final Rule (*89 FR 96364*), we proposed and finalized provisions for calculating the composite graft survival rate at *§ 512.428(b)(1).*

In our initial proposal in the 2024 Proposed Rule (*89 FR 43563*), we stated that we had considered incorporating a risk-adjustment methodology into our proposed composite graft survival equation, such as the one used by Scientific Registry of Transplant Recipients (SRTR) for 1-year post-transplant outcomes conditional on 90-day survival or constructing our own. We also stated at *89 FR 43563* that we were interested in comments on whether risk-adjustments were necessary, and which ones, such as transplant recipient and donor characteristics, would be significant and clinically appropriate in the context of our proposed approach. We received over 15 comments expressing concern that the lack of risk-adjustment in the composite graft survival rate metric could have adverse consequences and would add additional administrative burden. As described at *89 FR 96362,* many commenters expressed concern that the unadjusted composite graft survival rate does not account for the clinical risk factors of the transplant recipient or the donor; therefore, it may inadvertently lead to disparities in transplant access by incentivizing IOTA participants to select healthier patients for transplantation. Several commenters believe that the proposed measure misaligned with the model's goal of increasing kidney transplants in a more complex population without risk-adjusting for allograft and recipient factors. Without proper risk-adjustment, these commenters suggested the proposed measure could cause IOTA participants to be more risk averse with the types of organs they accept or disincentivize IOTA participants from transplanting candidates who have a higher likelihood of graft failure, such as older candidates or those with more comorbid conditions. Some commenters suggested specific transplant recipient and donor characteristics that CMS should risk-adjust for when calculating the proposed composite graft survival rate.

In the 2024 Final Rule (*89 FR 96363*), we stated that in light of commenters suggestions, we considered finalizing a risk-adjustment methodology that adjusted for donor age, recipient age, and recipient diabetes. However, we decided to finalize the provisions as proposed as we did not believe that adjusting for these three variables alone was appropriate. Organ availability affects kidney transplantation, leading transplant teams to expand the criteria for accepting organ donors.[3] In these circumstances, we believe that analysis of the impact of the donor's characteristics on graft survival becomes mandatory before incorporating a risk-adjustment methodology. Additionally, given that the IOTA Model is 6 years,

[2] We note that the definition and criteria for ''acceptable'' post-transplant outcomes has not been defined and we are seeking comment on how to define an acceptable level (for example, 1 standard deviation of the national risk-adjusted rate or some other way), as stated in section II.B.2.b(2) of this proposed rule.

[3] Olawade, D.B., Marinze, S., Qureshi, N., Weerasinghe, K., & Teke, J. (2024). Transforming organ donation and transplantation: Strategies for increasing donor participation and system efficiency. *European Journal of Internal Medicine. https://doi.org/10.1016/j.ejim.2024.11.010.*

and the measure is rolling, meaning that it measures the rolling total number of functioning grafts relative to the total number of adult kidney transplants performed for all 6 years, as described in the 2024 Final Rule at *89 FR 96324*, we wanted to continue discussions to ensure that this measure eventually includes a robust and appropriate risk-adjustment methodology. Furthermore, we continue to believe that the lack of risk-adjustment for PY 1 would be minimal in terms of impacting IOTA participants scores and note that IOTA participants do not owe a downside risk payment in PY 1, as described in *§ 512.430(b)(3)(i).* We also note that in the 2024 Final Rule at *89 FR 96364*, we stated that while we were finalizing our provision for calculating the composite graft survival rate as proposed, we would be stratifying the data from the composite graft survival rate measure to inform a risk-adjustment methodology for this measure and might consider future notice and comment rulemaking on this topic.

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. As such, in this proposed rule, we are proposing at § 512.428(b)(2) to include a risk-adjustment methodology in the composite graft survival rate calculation. Specifically, we propose 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, that includes at minimum the following:

- Transplant recipient characteristics:
  - ++ Age.
  - ++ Sex.
  - ++ Kidney function (eGFR/creatinine).
  - ++ Diabetes status.
  - ++ Hypertension with or without cardiovascular disease.
  - ++ Human leukocyte antigen (HLA) mismatch.
  - ++ 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.
  - ++ Donation after cardiac death.

We believe that the proposed transplant recipient and donor characteristics represent well-established, non-modifiable predictors that significantly influence graft survival independent of care quality. For example, advanced transplant recipient age increases mortality and cardiovascular complications, while sex-based differences in immune response and medication metabolism create distinct risk profiles requiring fair assessment.[4] [5] Diabetes, hypertension, and cardiovascular disease represent major outcome determinants present at transplantation that are largely beyond transplant hospitals' short-term control.[6] [7] [8] Donor age correlates with reduced nephron mass and shorter graft lifespan, while cause of death and donation type significantly affect both immediate function and long-term survival, creating substantial organ quality variation across centers.[9] Higher HLA mismatch increases rejection likelihood independent of clinical management quality, while elevated PRA levels indicate pre-existing sensitization creating immunological barriers that require intensive immunosuppression—both characteristics determined by factors largely beyond a kidney transplant hospital's control.[10] [11] Given the scarcity of donor organs and the IOTA Model's imperative to maximize transplant opportunities, risk-adjusted allocation strategies support accepting suboptimal immunological compatibility when clinically appropriate.[12]

We propose at § 512.428(b)(2)(ii)(A) that CMS would analyze the transplant recipient and donor characteristics as specified at proposed § 512.428(b)(2)(i)(A) and (B). We also propose at § 512.428(b)(2)(ii)(B) that CMS would then apply a risk score to each individual IOTA transplant patient, as defined at § 512.402, based on the analysis of the transplant recipient and donor characteristics at proposed § 512.428(b)(2)(ii)(A). Lastly, we propose at § 512.428(b)(2)(ii)(C)(*1*) and (*2*) that CMS would use the calculated composite graft survival rate risk scores identified at proposed § 512.428(b)(2)(ii)(B) 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.

We believe this systematic approach to risk-adjusting kidney transplantation ensures standardized care delivery while accommodating individual kidney transplant patient needs and optimizing long-term outcomes through evidence-based protocols, and continuous quality improvement initiatives. Risk-adjustment accounts for factors that are associated with the outcome, vary across providers, and are unrelated to quality of care, so that measure scores reflect true differences in quality of care.[13] 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. Through the proposed

[4] Schwager, Y., Littbarski, S.A., Nolte, A., Kaltenborn, A., Emmanouilidis, N., Kleine-Döpke, D., Klempnauer, J., & Schrem, H. (2019). Prediction of Three-Year Mortality After Deceased Donor Kidney Transplantation in Adults with Pre-Transplant Donor and Recipient Variables. *Annals of Transplantation, 24*, 273–290. *https://doi.org/10.12659/aot.913217*.

[5] So, S., Au, E.H., Lim, W.H., Lee, V.W., & Wong, G. (2020). Factors influencing Long-Term patient and allograft outcomes in elderly kidney transplant recipients. *Kidney International Reports, 6*(3), 727–736. *https://doi.org/10.1016/j.ekir.2020.11.035*.

[6] Schwager, Y., Littbarski, S.A., Nolte, A., Kaltenborn, A., Emmanouilidis, N., Kleine-Döpke, D., Klempnauer, J., & Schrem, H. (2019). Prediction of Three-Year Mortality After Deceased Donor Kidney Transplantation in Adults with Pre-Transplant Donor and Recipient Variables. *Annals of Transplantation, 24*, 273–290. *https://doi.org/10.12659/aot.913217*.

[7] So, S., Au, E.H., Lim, W.H., Lee, V.W., & Wong, G. (2020). Factors influencing Long-Term patient and allograft outcomes in elderly kidney transplant recipients. *Kidney International Reports, 6*(3), 727–736. *https://doi.org/10.1016/j.ekir.2020.11.035*.

[8] Nishio, A.G., Patel, A., Mehta, S., Yadav, A., Doshi, M., Urbanski, M.A., Concepcion, B.P., Singh, N., Sanders, M.L., Basu, A., Harding, J.L., Rossi, A., Adebiyi, O.O., Samaniego-Picota, M., Woodside, K.J., & Parsons, R.F. (2024). Expanding the access to kidney transplantation: Strategies for kidney transplant programs. *Clinical Transplantation, 38*(5). *https://doi.org/10.1111/ctr.15315*.

[9] Watson, C.J.E., Johnson, R.J., Birch, R., Collett, D., & Bradley, J.A. (2012). A Simplified Donor Risk Index for Predicting Outcome After Deceased Donor Kidney Transplantation. *Transplantation, 93*(3), 314–318. *https://doi.org/10.1097/tp.0b013e318 23f14d4*.

[10] Ibid.

[11] Schwager, Y., Littbarski, S.A., Nolte, A., Kaltenborn, A., Emmanouilidis, N., Kleine-Döpke, D., Klempnauer, J., & Schrem, H. (2019). Prediction of Three-Year Mortality After Deceased Donor Kidney Transplantation in Adults with Pre-Transplant Donor and Recipient Variables. *Annals of Transplantation, 24*, 273–290. *https://doi.org/10.12659/aot.913217*.

[12] Riley S, Zhang Q, Tse WY, Connor A, Wei Y. Using information available at the time of donor offer to predict kidney transplant survival Outcomes: A Systematic Review of Prediction Models. *Transplant International.* 2022;35. *https://doi:10.3389/ti.2022.10397*.

[13] So, S., Au, E.H., Lim, W.H., Lee, V.W., & Wong, G. (2020). Factors influencing Long-Term patient and allograft outcomes in elderly kidney transplant recipients. *Kidney International Reports,* 6(3), 727–736. *https://doi.org/10.1016/j.ekir.2020.11.035*.

risk-adjustment modeling, we believe an appropriate outcome rate is set for IOTA participants who care for kidney transplant patients with certain risk factors, decreasing the incentive to select younger, healthier patients for transplantation.

We seek comments on our proposed composite graft survival rate risk-adjustment methodology at proposed § 512.428(b)(2). We also seek 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.

We considered all recommendations made by public commenters in the 2024 Final Rule. For example, a commenter believed that CMS should risk-adjust for at least a small number of factors that would allow for a simple model that is understandable by including the biggest drivers for variation in outcomes and thereby disincentivize the creation of additional hurdles for more complex transplant recipients (*89 FR 96361*). The same commenter believed that a risk-adjustment model that includes age, ESRD vintage, and diabetes mellitus (y/n) would leverage currently available data and remain easily measurable and understood. We strongly considered this recommendation and chose to propose a similar approach with different factors to account for more scenarios and to reduce the chance of disincentivizing transplantation.

Multiple commenters in the 2024 Final Rule and some IOTA participants advocated for the adoption of the SRTR risk-adjustment methodology, which is presently utilized by both the Organ Procurement and Transplantation Network (OPTN) and CMS in existing programs. The SRTR risk-adjustment framework incorporates comprehensive adjustments for both transplant recipient and donor characteristics, undergoes annual updates to maintain currency, and is subject to validation and testing protocols. During each transplant program-specific report (PSR) cycle, the SRTR conducts a comprehensive refit of the graft survival prediction model, systematically evaluating numerous potential predictor variables to optimize the model's predictive accuracy and clinical relevance. The SRTR calculates the kidney donor risk index (KDRI) in accordance with the methodology established by Rao et al.[14] As such, we also considered, but did not propose, using SRTR's 1-year post-transplant outcomes risk-adjustment methodology for adult (18+) kidney graft survival with deceased and living donors, which includes a defined list of transplant recipient and donor characteristics included in the calculation that are updated periodically.[15] There is empirical support for sophisticated risk-adjustment methodologies like SRTR's, while acknowledging the need for ongoing refinement as unmeasured risk factors are identified and measurement precision improves.[16] [17] However, we believe this would require increased sophistication and attention from IOTA participants to interpret the additional information required and also require additional communications and education resources at transplant hospitals, potentially at Organ Procurement Organizations (OPO), and national levels.[18]

Additionally, SRTR implements more frequent model rebuilds in addition to refitting the models every 6 months. The purpose of rebuilding each cycle is to ensure that new transplant recipient and donor characteristics are incorporated into the risk-adjustment methodology. Therefore, for the purposes of risk-adjusting the composite graft survival rate, we considered, but did not propose, using only SRTR's post-transplant outcomes adult kidney model strata and most recently available set of coefficients. Alternatively, we also considered but did not propose utilizing a more limited set of characteristics than those employed by SRTR for simplification purposes.

A primary criticism of the SRTR risk-adjustment framework concerns the potential for encouraging risk aversion.[19] [20] [21] [22] [23] [24] Kidney transplant hospitals may prioritize statistical performance over kidney transplant waitlist patient access to care, potentially limiting transplant opportunities for kidney transplant waitlist patients who would benefit despite higher risk profiles.[25] There have been persistent questions about ''whether the OPTN data are adequate for risk-adjustments used in SRTR program-specific reporting.'' [26] While the current methodology provides adequate risk-adjustment for available data, the collection of additional risk factors such as local comorbidity indexes, community risk factors, cardiovascular risk factors, and anatomical abnormalities or vascular injury in donor kidneys could further

[14] Rao, P.S., Schaubel, D.E., Guidinger, M.K., Andreoni, K.A., Wolfe, R.A., Merion, R.M., Port, F.K., & Sung, R.S. (2009). A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index. *Transplantation, 88*(2), 231–236. *https://doi.org/10.1097/TP.0b013e3181ac620b.*

[15] Technical methods for the Program-Specific reports. (n.d.–b). *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/.*

[16] Axelrod, D.A., Schwantes, I.R., Harris, A.H., Hohmann, S.F., Snyder, J.J., Balakrishnan, R., Lentine, K.L., Kasiske, B.L., & Schnitzler, M.A. (2022). The need for integrated clinical and administrative data models for risk adjustment in assessment of the cost transplant care. *Clinical Transplantation, 36* (12), e14817. *https://doi.org/10.1111/ctr.14817.*

[17] Israni, A.K., Hirose, R., Segev, D.L., Hart, A., Schaffhausen, C.R., Axelrod, D.A., Kasiske, B.L., & Snyder, J.J. (2022). Toward continuous improvement of Scientific Registry of Transplant Recipients performance reporting: Advances following 2012 consensus conference and future consensus building for 2022 consensus conference. *Clinical Transplantation, 36* (8), e14716. *https://doi.org/10.1111/ctr.14716.*

[18] Technical methods for the Program-Specific reports. (n.d.–b). *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/.*

[19] Schenk, A.D., Logan, A.J., Sneddon, J.M., Faulkner, D., Han, J.L., Brock, G.N., & Washburn, W.K. (2022). Textbook Outcome as a Quality Metric in Living and Deceased Donor Kidney Transplantation. *Journal of the American College of Surgeons, 235*(4), 624–642. *https://doi.org/10.1097/xcs.0000000000000301.*

[20] Kasiske, B.L., Salkowski, N., Wey, A., Israni, A.K., & Snyder, J.J. (2018). Scientific Registry of Transplant Recipients program-specific reports: where we have been and where we are going. *Current Opinion in Organ Transplantation, 24*(1), 58–63. *https://doi.org/10.1097/mot.0000000000000597.*

[21] Jay, C., & Schold, J.D. (2017). Measuring Transplant Center Performance: the Goals Are Not Controversial but the Methods and Consequences Can Be. *Current Transplantation Reports, 4*(1), 52–58. *https://doi.org/10.1007/s40472-017-0138-9.*

[22] Snyder, J.J., Salkowski, N., Wey, A., Israni, A.K., Schold, J.D., Segev, D.L., & Kasiske, B.L. (2016). Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports. *American Journal of Transplantation, 16*(9), 2646–2653. *https://doi.org/10.1111/ajt.13783.*

[23] Bowring, M.G., Massie, A.B., Craig-Schapiro, R., Segev, D.L., & Nicholas, L.H. (2018). Kidney offer acceptance at programs undergoing a Systems Improvement Agreement. *American Journal of Transplantation, 18*(9), 2182–2188. *https://doi.org/10.1111/ajt.14907.*

[24] Abecassis, M.M., Burke, R., Klintmalm, G.B., Matas, A.J., Merion, R.M., Millman, D., Olthoff, K., & Roberts, J.P. (2009). American Society of Transplant Surgeons Transplant Center Outcomes Requirements—A Threat to Innovation. *American Journal of Transplantation, 9*(6), 1279–1286. *https://doi.org/10.1111/j.1600-6143.2009.02606.x.*

[25] Kasiske, B.L., Salkowski, N., Wey, A., Israni, A.K., & Snyder, J.J. (2018). Scientific Registry of Transplant Recipients program-specific reports: where we have been and where we are going. *Current Opinion in Organ Transplantation, 24*(1), 58–63. *https://doi.org/10.1097/mot.0000000000000597.*

[26] Schenk, A.D., Logan, A.J., Sneddon, J.M., Faulkner, D., Han, J.L., Brock, G.N., & Washburn, W.K. (2022). Textbook Outcome as a Quality Metric in Living and Deceased Donor Kidney Transplantation. *Journal of the American College of Surgeons, 235*(4), 624–642. *https://doi.org/10.1097/xcs.0000000000000301.*

enhance the accuracy and fairness of IOTA Model evaluations.[27] Given that the objective of the IOTA Model is to increase kidney transplant volume, we did not propose using SRTR's risk-adjustment methodology or using only SRTR's post-transplant outcomes adult kidney model strata and most recently available set of coefficients due to concerns that it creates stronger incentives for risk aversion compared to alternative approaches. Additionally, given that the composite graft survival rate is a rolling measure, we also had operational concerns in the use of SRTRs risk-adjustment methodology in future PYs.

We also considered but did not propose a risk-adjustment methodology that utilizes a Cox regression model,[28] which accounts for time-to-event data and can handle censored observations, making it a strong potential option for risk-adjustment in transplant outcome studies. In this methodology, censored observations [29] would include transplant recipients still alive at the end of the follow-up period, transplant recipients lost to follow-up before experiencing death or graft failure, and transplant recipients who withdrew from the study before the event occurred including two donor and five recipient variables.[30] Cox regression models have been cited for strong performance with extreme categories, discriminative power, and interpretable results.[31] [32] [33] This methodology also exhibits several inherent limitations, including restrictive assumptions concerning proportional hazards and linear effects of variables, inadequate handling of outliers within continuous variables and variable interactions, and constraints regarding the limited number of variables that can be incorporated into the modeling framework.[34] [35] While we recognize the importance of incorporating a time-to-event model in the risk-adjustment methodology to account for the length of graft survival, we chose not to propose a Cox regression model because it shows only moderate prediction accuracy overall and needs more validation.

We considered, but did not propose, a direct standardization risk-adjustment approach. This method applies standard population risk profiles [36] to all IOTA participants. Advantages to this method include simple interpretation and precedence in Care Compare.[37] Disadvantages are that it requires large sample sizes and is less precise for smaller kidney transplant hospitals. We chose not to propose this method because it could disadvantage smaller IOTA participants.

We considered, but did not propose, an indirect standardization (observed-to-expected ratios) risk-adjustment approach, which compares observed outcomes to expected outcomes based on a risk model. Advantages to this method are that it preserves competitive scoring while ensuring fairness, works well with small sample sizes, provides precise estimates, and has precedence with the ESRD Quality Incentive Program (QIP) Standardized Mortality Ratio (SMR).[38] [39] We chose not to propose this approach because of the complexity of designing a robust risk model.

We considered, but did not propose, a hierarchical logistic regression approach with indirect standardization. This approach models graft survival probability at the individual transplant recipient level and accounts for kidney transplant hospital-level clustering effects.[40] [41] It produces observed-to-expected ratios for fair comparison and is compatible with cumulative measure calculation. The hierarchical logistic regression statistical model structure we considered using is illustrated in Equation 1:

Equation 1: Considered Hierarchical Logistic Regression Equation

$$logit(P_{ij}) = \beta_0 + \beta_1(Age\_ij) + \beta_2(Diabetes\_ij) + \beta_3(DialysisVintage\_ij) + \beta_4(KDPI\_ij) + \beta_5(DCD\_ij) + \beta_6(PRA\_ij) + u\_j$$

Where:

P_{ij} = *probability of graft survival for kidney transplant patient i in IOTA participant j*

$u_j \sim N(0,\sigma_u^2$ *represents random IOTA participant—level effects*

β^0 = *intercept*

β^1–β^6 = *fixed effect coefficients for risk adjustment variables*

[27] Snyder, J.J., Salkowski, N., Wey, A., Israni, A.K., Schold, J.D., Segev, D.L., & Kasiske, B.L. (2016). Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports. *American Journal of Transplantation, 16*(9), 2646–2653. *https://doi.org/10.1111/ajt.13783.*

[28] 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 where the event of interest may encompass mortality, disease onset, or other clinically relevant occurrences.

[29] In the context of risk-adjustment, a censored observation refers to incomplete information about the true timing or occurrence of an outcome of interest, where only certain boundaries are known rather than the exact value. This phenomenon is particularly prevalent in healthcare risk adjustment models when tracking patient outcomes such as readmissions, complications, or mortality events. Properly accounting for censored observations through survival analysis methods is crucial in risk adjustment because ignoring censoring can lead to biased risk estimates, inaccurate patient stratification, and flawed predictive models that may unfairly penalize or reward healthcare providers based on incomplete outcome data.

[30] Senanayake, S., Kularatna, S., Healy, H., Graves, N., Baboolal, K., Sypek, M.P., & Barnett, A. (2021). Development and validation of a risk index to predict kidney graft survival: the kidney transplant risk index. *BMC Medical Research Methodology, 21*(1). *https://doi.org/10.1186/s12874-021-01319-5.*

[31] Ibid.

[32] Abd ElHafeez, S., D'Arrigo, G., Leonardis, D., Fusaro, M., Tripepi, G., & Roumeliotis, S. (2021). Methods to Analyze Time-to-Event Data: The Cox Regression Analysis. *Oxidative Medicine and Cellular Longevity, 2021*(1), 1–6. *https://doi.org/10.1155/2021/1302811.*

[33] Wey, A., Hart, A., Salkowski, N., Skeans, M., Kasiske, B.L., Israni, A.K., & Snyder, J.J. (2020). Posttransplant outcome assessments at listing: Long-term outcomes are more important than short-term outcomes. *American Journal of Transplantation, 20*(10), 2813–2821. *https://doi.org/10.1111/ajt.15911.*

[34] Senanayake, S., Kularatna, S., Healy, H., Graves, N., Baboolal, K., Sypek, M.P., & Barnett, A. (2021). Development and validation of a risk index to predict kidney graft survival: the kidney transplant risk index. *BMC Medical Research Methodology, 21*(1). *https://doi.org/10.1186/s12874-021-01319-5.*

[35] Scheffner, I., Gietzelt, M., Abeling, T., Marschollek, M., & Gwinner, W. (2020). Patient Survival After Kidney Transplantation: Important Role of Graft-sustaining Factors as Determined by Predictive Modeling Using Random Survival Forest Analysis. *Transplantation, 104*(5), 1095–1107. *https://doi.org/10.1097/tp.0000000000002922.*

[36] Standard population risk profiles represent a methodological framework that establishes a reference population to enable fair and meaningful comparisons between healthcare centers when patient populations exhibit different risk characteristics. The methodology employs all patients from all providers as the reference population, creating a uniform baseline against which all centers can be evaluated equitably. The process involves estimating the relationship between patient characteristics (represented as a vector of covariates X reflecting potential risk factors) and clinical outcomes for each healthcare center. This established relationship is then applied to all patients within the reference population to calculate expected outcomes as if every patient in the reference population had received treatment at each specific center under evaluation. Mathematically, this direct standardization approach can be expressed as $d\_c = (1/N) \times \Sigma\ \hat{p}\_c(X\_i)$, where d_c represents the standardized outcome for center c, N denotes the total number of patients in the reference population, and $\hat{p}\_c(X\_i)$ represents the estimated probability for patient i's characteristics at center c.

[37] Schokkaert, E., & Van De Voorde, C. (2008). Direct versus indirect standardization in risk adjustment. *Journal of Health Economics,* 28(2), 361–374. *https://doi.org/10.1016/j.jhealeco.2008.10.012.*

[38] Ibid.

[39] Scheffner, I., Gietzelt, M., Abeling, T., Marschollek, M., & Gwinner, W. (2020). Patient Survival After Kidney Transplantation: Important Role of Graft-sustaining Factors as Determined by Predictive Modeling Using Random Survival Forest Analysis. *Transplantation, 104*(5), 1095–1107. *https://doi.org/10.1097/tp.0000000000002922.*

[40] Hoffman, J.I. (2015). Survival analysis. In *Elsevier eBooks* (pp. 621–643). *https://doi.org/10.1016/b978-0-12-802387-7.00035-4.*

[41] Hoffman, J.I. (2015a). Logistic regression. In *Elsevier eBooks* (pp. 601–611). *https://doi.org/10.1016/b978-0-12-802387-7.00033-0.*

This equation risk-adjusts for age, diabetes status, dialysis vintage, Kidney Donor Profile Index (KDPI), Donation after Cardiac Death (DCD), which describes donors who are declared dead based on the cessation of circulatory and respiratory functions, and Panel Reactive Antibody (PRA). While we acknowledge that this approach demonstrates substantial technical merit, we believe that the level of complexity inherent in a hierarchical logistic regression statistical model structure would introduce operational risks and administrative burden. Transplant hospital-level variation may not be significant enough to warrant the added complexity,[42] as such, we did not believe this was appropriate to propose for the IOTA Model.

We further considered, but did not propose, using machine learning-based risk-adjustment methodology, which uses ensemble methods (random forests, gradient boosting) for risk prediction. Machine learning-based risk-adjustment methodology captures complex interactions and has high predictive accuracy, but we chose not to propose it due to concerns that stakeholders may resist the ''black box'' machine learning-based risk-adjustment methodology and the limited precedence in quality measurement or at CMS.[43]

We seek comment on the alternatives considered. Although we are not proposing to include a risk-adjustment methodology that also accounts for time-to-event data, we seek 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. We also seek 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.

In the 2024 Final Rule (*89 FR 96364*), we 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. Specifically, questions surrounded the current regulation at *§ 512.428(b)(1)(iii)(E)*, which states that CMS will exclude offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone) from the numerator. We clarified that this exclusion pertains to the offer phase of the transplant process. The actual transplant outcomes, when including a kidney, remain within the measurement scope. This interpretation ensures standardized application of the exclusion criterion while maintaining the measure's intended focus on kidney transplant outcomes, regardless of concurrent multi-organ status. We also noted that the denominator calculation, as finalized in the 2024 Final Rule, does not contain exclusions for multi-organ transplants, which allows for comprehensive tracking of all kidney transplant outcomes. 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.

In this proposed rule, we are proposing to update the regulation at § 512.428(b)(1)(iii)(E) to exclude multi-organ transplants (except for kidney/pancreas transplants) from the numerator. As a result, we are 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, we propose 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. We seek comment on our proposed definition of single-organ kidney transplant at proposed § 512.402.

We are proposing to exclude multi-organ transplants—procedures in which a kidney is surgically transplanted from deceased donor to a transplant recipient along with one or more organs transplanted simultaneously—except for kidney/pancreas transplants from the composite graft survival rate metric in recognition of the increased complexity of clinical outcomes associated with these procedures.[44] In acknowledgment that multi-organ transplantation represents a distinct clinical scenario with potentially different risk profiles, complication rates, and outcomes compared to single-organ kidney transplantation, we believe it would be methodologically sound to analyze multi-organ transplant recipients separately from single-organ kidney transplant and kidney/pancreas transplant recipients. We are proposing to include kidney/pancreas transplants because, although these procedures are associated with greater surgical complexity and higher perioperative risk, clinical evidence demonstrates improved recipient survival compared with kidney transplantation alone among patients with Type 1 Diabetes Mellitus.[45] Kidney/pancreas transplantation offers a potential cure for both diabetes and kidney failure in this population.[46] Additionally, the inclusion of kidney/pancreas transplants within the composite graft survival rate metric aligns with established SRTR methodology, which includes kidney/pancreas transplants while excluding other multi-organ transplant procedures from their graft survival criteria.[47] We further note that that including kidney/pancreas transplants in the composite graft survival rate metric is consistent with the efficiency domain as described at *§ 512.426(b)(1)(iii)(E)* where multi-organ kidney transplant offers (except for kidney/pancreas candidates that are also listed for kidney alone) are excluded from the organ offer acceptance rate ratio measure calculation.

We seek comment on our proposals at proposed §§ 512.428(b)(1)(iii)(E) and 512.428(b)(1)(iv)(A) to exclude multi-organ transplants except for kidney/pancreas transplants from the numerator and denominator when calculating the composite graft survival rate in the quality domain.

We considered retaining the inclusion of multi-organ transplantation in the calculation of the composite graft survival rate and solely revising the text

[42] Leyland, A.H., & Groenewegen, P.P. (2020b). Multilevel Modelling for Public Health and Health Services Research. In *Springer eBooks.* Springer Nature. *https://doi.org/10.1007/978-3-030-34801-4.*

[43] Weissman, G.E., & Maddox, K.E.J. (2023). Guiding risk adjustment models toward machine learning methods. *JAMA, 330*(9), 807. *https://doi.org/10.1001/jama.2023.12920.*

[44] Schold, J.D., & Mohan, S. (2021). A deeper dive into the impact of multiple-organ transplant policy on kidney transplant candidate prognoses. *American Journal of Transplantation, 21*(6), 2004–2006. *https://doi.org/10.1111/ajt.16508.*

[45] Ibid.

[46] Nagendra, L., Fernandez, C.J., & Pappachan, J.M. (2023). Simultaneous pancreas-kidney transplantation for end-stage renal failure in type 1 diabetes mellitus: Current perspectives. *World Journal of Transplantation, 13*(5), 208–220. *https://doi.org/10.5500/wjt.v13.i5.208.*

[47] *Technical methods for the Program-Specific reports.* (n.d.–b). *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/.*

of the regulation for clarification purposes. From 2000 to 2020 deceased donor kidney transplant volume doubled, while multi-organ transplants involving kidneys increased 6-fold during the same period.[48] Including multi-organ transplants in metrics could allow for more robust monitoring of multi-organ transplant outcomes and provide a more comprehensive assessment of transplant hospital capabilities and outcomes across all transplant types, ensuring a fair comparison of overall program performance.[49] However, we chose not to propose including multi-organ transplants because it would require rigorous analysis considering organ scarcity, dynamic decision-making, and heterogeneous practice patterns to develop risk-adjustment methodologies to account for multi-organ transplant allocation policies.[50]

We 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.[51] However, we chose not to proposed excluding all multi-organ transplants because we believe 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.[52] We seek comment on the alternatives considered. We also seek comment on whether CMS should include multi-organ transplants in the numerator and denominator and which multi-organ transplants should CMS include or exclude.

(b) Calculation of Points

In the 2024 Final Rule (*89 FR 43518*) that established the IOTA Model, we acknowledged commenter concerns about the proposed points allocation for the composite graft survival rate, arguing that it unfairly penalizes transplant hospitals that accept higher-risk patients and suggesting modifications including lowering the threshold for maximum points from the 80th to 60th percentile for IOTA participants (*89 FR 96365*). In response to comments, we finalized an alternate scoring methodology, such that IOTA participants would be awarded points based on the national quintiles, as outlined in Table 1, such that IOTA participants that perform—

- At or above the 80th percentile would earn 20 points;
- In the 60th percentile to below the 80th percentile would earn 18 points;
- In the 40th percentile to below the 60th percentile would earn 16 points;
- In the 20th to below the 40th percentile would earn 14 points;
- In the 10th to below the 20th percentile would earn 12 points; and
- Below the 10th percentile would receive 10 points for the composite graft survival rate.

TABLE 1: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Points Earned
80^{th} Percentile $\leq$	20
$60^{th} \leq$ and $< 80^{th}$ Percentile	18
$40^{th} \leq$ and $< 60^{th}$ Percentile	16
$20^{th} \leq$ and $< 40^{th}$ Percentile	14
$10^{th} \leq$ and $< 20^{th}$ Percentile	12
$< 10^{th}$ Percentile	10

In addition, we stated that we recognized that for PY 2 and future PYs there would be more events and a longer time horizon and plan to implement a more robust methodology that could account for both the likelihood of graft failure based on the donor and the recipient and could account for relative benefits of transplantation over remaining on dialysis (*89 FR 96365*). We direct readers to the 2024 Final Rule for a full discussion of this policy, our rationale for this approach, and alternatives considered (*89 FR 96364* through *96366*).

Upon further review of our methodology, we are proposing to modify the composite graft survival rate scoring methodology to allow for a more even scoring distribution for IOTA participants. Specifically, we propose in Table 1 to paragraph (d) at § 512.428 that 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.

We propose that points continue to be awarded based on national quintiles, as outlined in Table 2. We maintain our belief that utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as described in *42 CFR 512.430(b),* where average performing IOTA participant earns 10 points out of 20, 50 percent of the total possible points. We recognize that there is an upper limit to the benefits of quality, and quintiles combine the highest 20 percent of performers in a point band.

In accordance with *§ 512.428,* we propose the following updates to the allocation of points for the composite graft survival rate in Table 1 to paragraph (d) at § 512.428, as illustrated in Table 2:

- 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.

[48] Husain, S. A., Hippen, B., Singh, N., Parsons, R. F., Bloom, R. D., Anand, P. M., & Lentine, K. L. (2023). Right-Sizing multiorgan allocation involving Kidneys. *Clinical Journal of the American Society of Nephrology, 18*(11), 1503–1506. *https://doi.org/10.2215/cjn.0000000000000242.*

[49] Ibid.

[50] Schold, J. D., & Mohan, S. (2021). A deeper dive into the impact of multiple-organ transplant policy on kidney transplant candidate prognoses. *American Journal of Transplantation, 21*(6), 2004–2006. *https://doi.org/10.1111/ajt.16508.*

[51] Callaghan, C. J., Ibrahim, M., Counter, C., Casey, J., Friend, P. J., Watson, C. J., & Karydis, N. (2021). Outcomes after simultaneous pancreas–kidney transplantation from donation after circulatory death donors: A UK registry analysis. *American Journal of Transplantation, 21*(11), 3673–3683. *https://doi.org/10.1111/ajt.16604.*

[52] Ibid.

- 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

Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as described in *42 CFR 512.430(b),* where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 10 points out of 20, 50 percent of the total possible points. We recognize that there is an upper limit to the benefits of quality, and quintiles combine the highest 20 percent of performers in a point band.

Additionally, in the 2024 Final Rule (*89 FR 96379*), we stated that we would continue to assess our quality domain methodology and how to best balance incentives in the efficiency domain and quality domain and address a new or updated policy pursuant to future notice and comment rule making. Furthermore, as proposed in section II.B.2.b.(2).(a). of this proposed rule, we are proposing to incorporate a risk-adjustment methodology to the calculation of the composite graft survival rate measure. As such, we believe that the proposed allocation of points, as illustrated in Table 2, is necessary to account for the proposed composite graft survival rate risk-adjustment methodology, as described in section II.B.2.b.(2).(a). of this proposed rule, and best balances incentives in the quality domain.

We considered applying a two-scoring system in which we 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 as described at § 512.426(c). In this considered two-scoring system, the achievement score would reflect the proposed scoring approach on the composite graft survival rate, as illustrated in Table 2 of this section. For improvement scoring on the composite graft survival rate, we considered the following methodologies:

- In accordance with the organ offer acceptance rate ratio improvement scoring methodology at *§ 512.426(c)(2)(ii).*
- Improvement relative to national ranking from previous PY.
- Improvement over 2 PYs. In this methodology, improvement scoring would only be awarded twice (PYs 4 and 6) and would measure improvement by comparing PYs 1–2 to PYs 3–4 and PYs 3–4 to PYs 5–6.

We considered applying a two-scoring system in which we would determine an achievement score and improvement score and award the point equivalent to the higher value between the two scores because we recognize that if an IOTA participant does not do well one PY on the composite graft survival rate, as described at *§ 512.428(b)(1),* that it may be difficult for it to improve during the model performance period. However, we chose not to propose this methodology (two-scoring system) because we still had concerns over our ability to measure improvement year-over-year due to potentially small numbers. Furthermore, given that we are proposing to incorporate a risk-adjustment methodology, as proposed in section II.B.2(b)(2)(a) of this proposed rule, we believe that our proposed scoring approach rewards both achievement and improvements and is a more rigorous scoring methodology. Although we are not proposing to include this alternative, we seek comment on whether a two-scoring system methodology would be appropriate for the composite graft survival rate and the best approach for measuring improvement.

We seek comment on our proposed composite graft survival rate scoring methodology at proposed Table 1 to Paragraph (d) at § 512.428 for purposes of assessing quality domain performance for each IOTA participant. We also seek comments on alternatives considered. Additionally, we seek 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, 1 standard deviation of the national risk-adjusted rate or some other way).

3. Payment

a. Background

For the IOTA Model, we proposed and finalized an alternative payment model (APM) structure that incorporates both upside and downside risk to existing Medicare fee-for-service (FFS) payments for kidney transplantations. The IOTA Model will test whether performance-based payments, including the potential for an upside or downside risk payment, to IOTA participants increases access to kidney transplants for attributed patients while preserving or enhancing quality of care and reducing kidney transplant hospital expenditures.

In the 2024 Final Rule (*89 FR 43518*), we finalized provisions regarding downside risk payments and other payments as described in *§ 512.430,* where, we specified the methodologies for upside risk payments, neutral zone, and downside risk payments for IOTA participants. For upside risk payments, if the IOTA participant's final performance score is 60 points or above, CMS will calculate the IOTA participant's upside risk payment by subtracting 60 from the IOTA participant's final performance score, dividing the resulting amount by 40, multiplying the calculated amount by $15,000 and multiplying that amount by the total number of Medicare kidney transplants performed by the IOTA participant during the relevant PY. For downside risk payments, beginning in PY 2, CMS will calculate the downside risk payment by subtracting the IOTA participant's final performance score from 40, divide that number by 40, multiplying the resulting amount by $2,000 and multiplying that amount by the total number of Medicare kidney transplants performed by the IOTA participant during the relevant PY.

b. Alternative Payment Design

In the 2024 Final Rule (*89 FR 96383*), CMS proposed and finalized two-sided performance-based payments for ''Medicare kidney transplants,'' defined at *§ 512.402* as kidney transplants furnished to attributed patients whose primary or secondary insurance is Medicare FFS, as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651 and 652.

In our initial proposal in the 2024 Proposed Rule (*89 FR 43570*), we stated that we had considered including beneficiaries with Medicare Advantage (MA) as well in the definition of Medicare kidney transplants. As stated at *89 FR 96382,* we decided to finalize the policy as proposed as we did not believe that the additional incentive effects from including MA in the calculation for upside and downside risk payments were necessary at that point to provide sufficient incentive to test the model. We noted our plan to further engage with MA plans to think about the incentives in the IOTA Model and those set up by MA plans. We also planned to monitor relative enrollment of beneficiaries who receive kidney transplants in Medicare FFS as opposed to MA to see if further policy changes would be necessary for future years of the IOTA Model.

Since publication of the 2024 Final Rule, CMS has continued to assess its position regarding the potential inclusion of beneficiaries enrolled in MA within the definition of Medicare kidney transplants for several key reasons. This ongoing evaluation reflects CMS's commitment to monitoring changes in MA enrollment trends, analyzing potential impacts on model incentives and Medicare Trust Fund savings, and considering the operational and statutory implications of such an inclusion. CMS is soliciting public comment on this issue more broadly, on whether to include MA beneficiaries within the IOTA model, as well as on the specific considerations and requests for input if CMS were to proceed with such an approach.

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

Per the Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, Medicare FFS enrollment of the total ESRD population enrolled in Medicare is currently about 45 percent in 2024 and is projected to drop to approximately 40 percent by 2028. This means that updating the definition of Medicare kidney transplant would increase the maximum potential upside risk payments, per the definition in § 512.430(b)(1)(iv), for an IOTA participant given that the number of Medicare kidney transplants performed would on average also be increasing. 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 could make this change to balance our goals of creating a strong incentive for IOTA participants to increase their number of kidney transplants and ensure savings for the Medicare Trust Fund. We seek comment on our 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.

While there may be benefits to including kidney transplants furnished to MA beneficiaries in the calculation for the upside risk payment and downside risk payment, CMS continues to consider potential concerns or disadvantages. One potential issue is whether the payments made under such an approach could affect the contracting relationship between a Medicare Advantage organization (MAO) and the IOTA participant. We seek feedback from both IOTA participants and from MAOs about any potential effect that inclusion of beneficiaries with MA 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 MA organizations and their contracted providers. At the same time, CMS is interested in the potential in achieving greater alignment between MA and Medicare FFS payment methodologies.

Given the factors described in this section, CMS is soliciting comments from a broad range of stakeholders and interested parties, including MA plans, beneficiary advocates, healthcare providers, and industry experts. We are particularly interested in comments on how MA could play a role in the IOTA Model. Specifically, we are inviting public comment on the following:

- 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 MA inclusion 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 MA inclusion 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?

We extend our sincere appreciation in advance to all commenters, as their valuable feedback will serve to inform future CMS policy actions in this domain.

c. Performance-Based Payment Method

(1) Determine Final Performance Score Range Category

In the 2024 Final Rule (*89 FR 96384*), we 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. Additionally, we

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

We previously finalized for PYs 2 through 6 that an IOTA participant would qualify for the neutral zone if their final performance scores were between 41 and 59 points (inclusive) at *§ 512.430(b)(2)(ii),* as illustrated in Table 3. Since publication some IOTA participants have expressed confusion about final performance scores of 40 points and 60 points. In this proposed rule, we are proposing to update this provision to clarify language about final performance scores of 40 points and 60 points. Given the final performances scores described in Table 3, a score of 40 points results in zero downside risk payments and a score of 60 points results in zero upside risk payments. As a result, we are proposing to clarify the language in the rule to address this point and to further clarify the endpoints where an IOTA participant could receive an upside risk payment, be in the neutral zone, or receive a downside risk payment.

We propose at § 512.430(b)(1) to clarify that 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. Additionally, we propose at § 512.430(b)(2)(ii) to clarify that 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. Finally, we propose at § 512.430(b)(3) to clarify that 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.

We seek comment on our proposals at proposed § 512.430(b)(1), 512.430(b)(2)(ii), and 512.430(b)(3)(i) 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.

(2) Downside Risk Payment

In the 2024 Final Rule (*89 FR 96386*), we finalized provisions regarding downside risk payments and other payments as described in *§ 512.430.* Additionally, we finalized the definition of downside risk payment and established the methodology for its calculation. Since publication, we recognized that this section contains a typographical error that should be corrected regarding the deadline for downside risk payments and lacks specificity regarding what happens if the IOTA participant fails to make the downside risk payment for a given PY.

Therefore, we propose to update the provision at § 512.430(d)(6)(ii) to clarify that the IOTA participant must pay the downside risk payment to CMS in a single payment within 60 days, rather than at least 60 days, after the date on which the demand letter is issued. Where the IOTA participant fails to repay CMS in full for all monies owed, CMS would invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, pursuant to 31 U.S.C. 3711(g).

We seek comment on our 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.

(3) Extreme and Uncontrollable Circumstances

In the 2024 Final Rule (*89 FR 96389*), we finalized provisions regarding a policy related to Extreme and Uncontrollable Circumstances (EUC) at *§ 512.436.* We finalized that for the IOTA Model, CMS would apply determinations made under the QPP with respect to whether an extreme and uncontrollable circumstance has occurred and the affected area during the PY and that CMS has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas. If CMS determined then that an EUC occurred, CMS could then reduce the amount of the IOTA participant's downside risk payment, if applicable, prior to recoupment and calculate that reduction based on the percentage of total months during the PY affected by the extreme and uncontrollable circumstance and the percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance.

Since publication of the 2024 Final Rule, CMS has been reviewing its policy towards EUC events. The current EUC policy for the IOTA Model reflects the policy used for many accountable care organization (ACO) type models, including the ACO Realizing Equity, Access, and Community Health (ACO REACH) and Kidney Care Choices (KCC) Models. However, CMS recognizes that the policies used for the QPP may not be appropriate for the IOTA Model, given that the QPP policies may not account for broader impacts that an EUC might have on an IOTA participant's ability to perform in the model if allocation systems were disrupted due to an emergency or if there were disaster conditions that could disproportionately affect post-transplant outcomes. The current provision only potentially reduces downside payments and does not account for any change in the model inputs or reporting period that may affect an IOTA participant's performance score if their ability to perform on one of more of the measures were disrupted by an EUC event.

Therefore, we propose to update the provision at § 512.436(a)(1) to state that CMS may, at its sole discretion, apply flexibilities if the IOTA participant is located in an emergency area during an emergency period, as those terms are defined in section *1135(g) of the Act,* for which the Secretary has issued a waiver under section 1135 of the Act and if the IOTA participant is located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act. Additionally, we propose at § 512.436(a)(2) that CMS has the sole discretion to determine the time period during which payment and reporting

flexibilities are provided to the IOTA participant. Finally, we propose at § 512.436(b) that CMS may, at its sole discretion, adjust the direction and the magnitude of the upside or downside risk payments, if applicable, prior to recoupment or payment, for the IOTA participant if the IOTA participant is participating in the IOTA Model when CMS has declared such an emergency period.

We seek comment on our 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. We also seek 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.

4. Other Requirements

a. Transparency Requirements

(1) Publication of Selection Criteria for Kidney Transplant Evaluations and Waitlisting

In the 2024 Final Rule (*89 FR 96394*) that established the IOTA Model, we finalized that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1 at § 512.442(a). Additionally, we discussed commenters' suggestions to provide IOTA participants with flexibility in updating waitlist selection criteria and balancing accuracy with resource constraints. We direct readers to the 2024 Final Rule for a full discussion of this policy, a summary of the comments received, and our responses to those comments (*89 FR 96394* through *96397*).

To advance transparency for individuals seeking transplant waitlist access and to improve patient health literacy regarding transplant program evaluation processes, we propose to revise § 512.442(a). Specifically, we are proposing 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, we propose 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. The proposed modifications aim to improve patient health and safety while reducing disparities in access to transplant evaluations and seek to strengthen the transparency framework within transplant program evaluation processes, thereby facilitating improved patient understanding and equitable access to transplant services.

In recognition that transplant hospitals may make changes to its patient selection criteria for determining a patient's suitability for placement on a waitlist we believe that this proposed provision would capture these changes and ensure that the information on its website is up to date in future PYs. We also believe this policy would address commenters' suggestions and provide flexibility in updating its waitlist selection criteria on its website. We seek comment on these proposals at proposed § 512.442(a)(1) and (2).

We alternatively considered requiring IOTA participants to update its publicly posted patient selection waitlist criteria to ensure that this information on its websites remain current within timeframes of 30 days, 60 days, or 90 days following any modification. We acknowledge that these alternative timeframes would provide more accurate and timely information while facilitating informed patient decision-making. However, we are proposing that IOTA participants must review and update its publicly posted patient selection waitlist criteria by the end of each relevant PY to align with current and proposed publication requirements for patient selection criteria, as described in section II.B.4.a.(1). of this proposed rule, in the IOTA Model. We seek public comment on the alternatives considered.

If a transplant program performs living donor transplants, the transplant program's living donor selection criteria must be consistent with the general principles of medical ethics. The program must use written donor selection criteria to determine the suitability of candidates for donation. Transplant programs must also ensure that a prospective living donor receives a medical and psychosocial evaluation, document in the living donor's medical records the living donor's suitability for donation, and document that the living donor has given informed consent. We recognize 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, we propose that those IOTA participants must publicly post on its website its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients by the end of PY 2 at § 512.442(a)(3)(i). For all subsequent PYs, we propose 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.

We believe requiring IOTA participants that perform living donor kidney transplants to publicly post on their website its 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. Additionally, we believe this requirement would empower patients by providing them with clear information about what criteria their kidney transplant hospital uses to assess living donors, enabling patients, families, and referring physicians to better prepare potential donors and understand the evaluation process, which could ultimately lead to more successful living donor kidney transplant outcomes. We seek comment on these proposals at proposed § 512.442(a)(3)(i) and (ii). Finally, we propose finalizing these requirements only if they are not redundant with other Department of Health and Human Services (HHS) guidance.

We alternatively considered requiring IOTA participants to update its publicly posted living donor selection criteria to ensure that this information on its websites remains current within timeframes of 30 days, 60 days, or 90 days following any modification. We recognize that this alternative would provide more accurate and timely information while facilitating informed patient decision-making processes. However, we proposed that IOTA participants must review and update their publicly posted living donor selection criteria by the end of each relevant PY to align with current and proposed publication requirements for patient selection criteria, as described in section II.B.4.a.(1). of this proposed rule, in the IOTA Model. We seek public comment on the alternatives considered.

As previously suggested by commenters in the 2024 Final Rule (*89 FR 96396*), we 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. We 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. While we are not proposing to provide standardized waitlist selection criteria or living donor selection criteria templates that IOTA participants would be required to use, we are seeking public 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,* we seek 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. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that to enable CMS to evaluate the Innovation Center models as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we would use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models (85 FR 61124). We also stated that, consistent with section 1115A(b)(4)(B) of the Act, 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. We stated that the data to be disseminated would include, but would not be limited to, 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. We finalized these policies in *42 CFR 512.140(a).*

Consistent with these provisions, in the 2024 Final Rule (*89 FR 96403*) that established the IOTA Model, we finalized our proposals to publish results from all PYs of the IOTA Model. Specifically, we stated that, for each PY, we intend to identify each IOTA participant for the PY and to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant on the IOTA Model website annually, as they become available (*89 FR 96403*). We maintain our belief that this not only meets CMS requirements but also demonstrates transparency for the transplant community.

Adding to these provisions, we propose to publish IOTA participant waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this proposed rule, on the IOTA Model website. Specifically, for each PY, we intend to publish waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this proposed rule, for each IOTA participant on the IOTA Model website by the end of the second quarter of each subsequent PY. We propose to finalize this requirement only if they are not redundant with other HHS guidance. We believe that the release of this information on the IOTA Model website would inform the public about IOTA participants' selection criteria while in the IOTA Model. Furthermore, we believe 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, we note that this would supplement, not replace, the publication of selection criteria requirements in the IOTA Model.

We seek comment on our proposal to post this information to the IOTA Model website, as well as the information we intend 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. A provider may decline an organ offer for any number of reasons; [53] however, declining without disclosing the rationale to the patient may miss an important opportunity for shared decision-making.

After 3 years on the waiting list, approximately 27 percent of kidney transplant waitlist patients receive a deceased donor kidney transplant (DDKT), while 33 percent remain on the waitlist.[54] Communication with waitlisted patients is limited, typically focusing only on discussing eligibility requirements and notifying them when a transplant program plans to accept an organ offer.[55] [56] Furthermore, the National Academy of Sciences, Engineering, and Medicine (NASEM) released a significant report in 2022 titled ''Realizing the Promise of Equity in the Organ Transplantation System.'' [57] The report put forth several key recommendations to enhance transparency and patient engagement in the organ transplantation process. Notably, it called for transplant hospitals to increase transparency with patients regarding declined organ offers, including providing specific details about the number of declined offers and the rationale behind these decisions. Secondly, the report advocated for modifications to the OPTN contract, emphasizing the need for transplant hospitals to actively involve patients in the decision-making process when accepting or rejecting organs.

We also note the recent release of two studies related to notifying patients on the waiting list about declined organ offer, since we issued the 2024 Proposed Rule. One study conducted interviews with patients and nephrologists about this issue of organ offer transparency.[58] This study found that among 755 patient respondents surveyed, 64 percent expressed a preference to

[53] Reasons for declining include concerns about the quality of the donor organ, such as, donor comorbidity, evidence of disease or injury, or other clinical factors that could affect long-term graft survival. Providers may also decline an offer if the organ is not compatible with the candidate's blood type or antibody profile, which could increase the risk of rejection. Patient-specific factors may also play a role, such as the candidate not being medically stable for surgery at the time of the offer, not meeting weight or other health requirements, or having unresolved infections or comorbidities. In some cases, logistical issues like timing, transport of the organ, or operating room availability may contribute to a declined offer.

[54] Lentine, K.L., Smith, J.M., Miller, J.M., Bradbrook, K., Larkin, L., Weiss, S., Handarova, D.K., Temple, K., Israni, A.K., & Snyder, J.J. (2023). *OPTN/SRTR 2021 Annual Data Report: Kidney. American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 23*(2 Suppl 1), S21–S120. *https://doi.org/10.1016/j.ajt.2023.02.004.*

[55] Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. *https://stars.library.ucf.edu/etd2020/175/.*

[56] Rasheed, H.A., Pensler, M., Diaz, S., Roney, E., Barrett, M., & Sonnenberg, E.M. (2024). Organ Offer Review Cards: Improving Transparency on the Kidney Transplant Waitlist. *Clinical Transplantation, 38*(7). *https://doi.org/10.1111/ctr.15388.*

[57] National Academies of Sciences, Engineering, and Medicine. (2022a). *Realizing the Promise of Equity in the Organ Transplantation System* (K.W. Kizer, R.A. English, & M. Hackmann, Eds.). National Academies Press. *https://doi.org/10.17226/26364.*

[58] Husain, S.A., Rubenstein, J.A., Ramsawak, S., Huml, A.M., Yu, M.E., Maclay, L.M., Schold, J.D., & Mohan, S. (2025). Patient and Provider Attitudes Towards Patient-Facing Kidney Organ Offer Reporting. *Kidney International Reports, 10*(4), 1122–1130. *https://doi.org/10.1016/j.ekir.b2025.b01.013.*

receive organ offer reports. Of the total patient respondents, 87 percent indicated that transplant hospitals should be mandated to inform candidates about the organ offers they receive, while 62 percent specified that candidates should be notified following each individual offer. Additionally, 73 percent of nephrologists reported that they believe patients should be provided with offer information. The second study, conducted at the University of Michigan in 2022, developed and evaluated an innovative Organ Offer Review Card (OORC) designed to enhance transparency in kidney transplant waitlist processes.[59] In response to the 2022 NASEM recommendations for increased accountability in organ offer decisions, researchers created a prototype tool that summarizes patients' organ offers and reasons for decline over a 6-month period. This study employed a cross-sectional survey design to assess patients' perceptions, attitudes, and feedback regarding the OORC, while also examining perspectives on shared decision-making for organ offers. The survey found that of 60 randomly selected patients, 43 were reached by phone and 17 (39.5 percent) completed the survey, almost all of whom believed it was important to be involved in the decision-making process about organ offers and all of them wanted to understand why organs were declined on their behalf. The study further found that a vast majority of patients believe the information enhanced their understanding of the transplant process and believed that seeing this information would increase their trust in the transplant hospital. While these two studies have limited sample size, they represent a growing interest in how to foster organ offer transparency and patient-centered care.

As described in the 2024 Final Rule (*89 FR 96397*), we proposed to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries regarding the volume of organ offers received on their behalf while on the waitlist. Specifically, we proposed that for each month an organ is offered to an IOTA waitlist patient who is a Medicare beneficiary, 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, we did not finalize this transparency requirement to consider alternatives, such as an alternative frequency of sharing declined organ offers with the Medicare beneficiary. We also stated that we remain invested in evaluating alternative transparency opportunities for patients on the waiting list with the transplant community to fulfill this important need. We direct readers to the 2024 Final Rule for more information on the stakeholder comments regarding that proposal and our responses to those comments (*89 FR 96397* through *96403*).

Based on the feedback we received, we are proposing an alternative approach for the model. Specifically, for PYs 3 through 6 we propose 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, we propose to define ''eligible IOTA waitlist beneficiaries'' at § 512.402 as IOTA waitlist patients, as defined at *§ 512.402,* who are Medicare beneficiaries and meet all of 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.

We note that our rationale for this proposal is explained further later in this section. We seek comment on our proposed definition of eligible IOTA waitlist beneficiaries at proposed § 512.402.

We are proposing that, beginning in PY 3, IOTA participants would be required to provide notification of declined organ offers for eligible IOTA waitlist beneficiaries, as defined at proposed § 512.402, who are on their waitlist every 6 months, starting July 1 of PY 3, subject to the following conditions. IOTA participants would only have to notify eligible IOTA waitlist beneficiaries with at least 3 years of accrued waiting time. IOTA participants would have to provide this notification every 6 months after that time period. For example, if an eligible IOTA waitlist patient has 2 years and 11 months of accrued waiting time on July 1 of PY 3, the IOTA participant would not need to provide this notification to that eligible IOTA waitlist patient because they have not accrued 3 years of waiting time. Alternatively, if an eligible IOTA waitlist patient has 3 years and 11 months of accrued waiting time on July 1 of PY 3, the IOTA participant would need to provide this notification to that eligible IOTA waitlist patient because they have accrued 3 years of waiting time. This proposed timeframe is designed to balance between the operational burden for IOTA participants and when eligible IOTA waitlist beneficiaries could start getting transplantable 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, we propose 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)[60] 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)[61] 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;* and
- Potential avenues to accelerate access to transplant (for example,

[59] Rasheed, H.A., Pensler, M., Diaz, S., Roney, E., Barrett, M., & Sonnenberg, E.M. (2024). Organ Offer Review Cards: Improving Transparency on the Kidney Transplant Waitlist. *Clinical Transplantation, 38*(7). *https://doi.org/10.1111/ctr.15388.*

[60] As defined by the OPTN, the percent PRA value is a measure of a patient's level of sensitization to HLA antigens. It is the percentage of cells from a panel of blood donors against which a potential recipient's serum reacts. The PRA reflects the percentage of the general population that a potential recipient makes antibodies (is sensitized) against. For example, a patient with a PRA of 80 percent will be incompatible with 80 percent of potential donors. Kidney patients with a high PRA are given priority on the waiting list. The higher the PRA, the more sensitized a patient is to the general donor pool, and thus the more difficult it is to find a suitable donor. A patient may become sensitized as a result of pregnancy, a blood transfusion, or a previous transplant.

[61] Refusal reasons, as defined by the OPTN, are number codes used on a match run to show the reason an organ was not accepted for a potential transplant recipient (PTR) receiving the offer.

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).

We believe 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. We note that we did not finalize this provision in the 2024 Final Rule and stated that we were very interested in transparency, but due to the many concerns that we received, we recognized 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*). We believe though that circumstances have changed relative to when we wrote the 2024 Final Rule for a few reasons:

First, the IOTA Model has already started. The 2024 Final Rule that established the IOTA Model was finalized in December 2024 and IOTA participants were notified of their participation status. IOTA participants have had time to implement their care models. Additionally, IOTA participants would have plenty of notice of CMS' intent in this area, with approximately 18 months from the release date of this proposed rule in Fall 2025 until the start of PY 3 on July 1, 2027, to implement the necessary processes to implement these proposed notification requirements, if finalized.

Next, we believe that this updated provision that we are proposing is responsive to many of the administrative burden concerns that were raised by commenters in response to what we originally proposed in the 2024 Proposed Rule. For example, in this proposed rule we are proposing that the transparency into kidney transplant organ offers requirement would only apply for eligible IOTA waitlist beneficiaries, as defined in section II.B.4.a.(3). of this proposed rule, rather than all IOTA waitlist patients who are Medicare beneficiaries, and IOTA participants would only be required to notify eligible IOTA waitlist beneficiaries every 6 months, rather than monthly.

Additionally, we have been working with the Health Resources and Services Administration (HRSA) with operational assistance to help to 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.

We considered requiring that an IOTA participant begin providing notification of declined organ offers 3 years from when a beneficiary started dialysis, but did not propose that as we know some beneficiaries get onto the waitlist before they start dialysis. We also considered proposing 1 or 2 years of waitlist time, as well as 4 or 5 years, but 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. We seek comment on the alternative considered.

We considered proposing to require IOTA participants to provide this notification to eligible IOTA waitlist beneficiaries once they join the list or with just 1 year or 2 years of waiting list time but decided to propose 3 years to balance informing these patients with the workload for IOTA participants. We also considered proposing other timeframes for potentially notifying eligible IOTA waitlist beneficiaries about kidney transplant organ offers including monthly, quarterly, or annually, but 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, as described in section II.B.4.a.(5). of this proposed rule.

Subsequently, we 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. For example, a notification in January would include the number of received and accepted kidney transplant offers by the IOTA participant from July 1 to December 31, alongside the number of kidney transplant organ offers that the individual eligible IOTA waitlist beneficiary received during that same time frame. We believe that providing total kidneys accepted by an IOTA participant would help provide a comparison for when eligible IOTA waitlist beneficiaries receive organ offer notifications every 6 months. In recognition of the additional reporting complexity this variation would introduce for IOTA participants, we did not propose this alternative considered.

We considered limiting this proposed requirement exclusively to kidney transplant organ offers that were ultimately transplanted; however, we 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. We also 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 wanted to err on the side of providing greater transparency to eligible IOTA waitlist beneficiaries. We further considered excluding multi-organ offers from this provision; however, we did not propose such exclusion because we wanted to ensure that eligible IOTA waitlist beneficiaries would receive a more complete perspective regarding their care.

We considered requiring other explanations for why each kidney transplant organ offer was declined, in order to provide additional specificity where appropriate but decided to propose OPTN refusal codes in order to provide a standardized approach for IOTA participants using a format they are already familiar with. We also considered requiring cumulative information of organ offers declined since the eligible IOTA waitlist beneficiary was added to the IOTA participant's waitlist but were unsure if that would provide additional useful information for these beneficiaries.

Lastly, we 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). We think 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. Additionally, a standardized template would enhance beneficiary understanding by presenting complex medical information in a consistent, accessible format across all IOTA participants, while also facilitating more efficient CMS oversight

and enabling better aggregation of beneficiary communication data for program evaluation and quality improvement initiatives. We also recognize that requiring IOTA participants to use a CMS-provided notification template presents certain considerations that merit evaluation. While standardization offers benefits, we recognize that it may present challenges in addressing diverse patient populations, varying literacy levels, and unique clinical circumstances that could benefit from tailored communication approaches. Furthermore, a standardized notification template may need to be designed with sufficient flexibility to accommodate the different operational capabilities, existing communication systems, and established beneficiary relationships that individual IOTA participants have developed to avoid potential implementation challenges or reduced effectiveness in patient communication. While we are not proposing to provide a standardized notification template that IOTA participants would be required to use, we are seeking public 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, we seek 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, we are proposing 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. We propose at § 512.442(b)(2)(i) IOTA participants must give eligible IOTA waitlist beneficiaries the opportunity to opt out of receiving this notification. We propose 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 all of 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.

We note that our rationale for this proposal is explained further later in the section.

We also propose 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 eligible IOTA waitlist beneficiary received the notification specified in proposed § 512.442(b)(1);
- The method by which the notification was delivered; and
- The date by which the notification was delivered.

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

We 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 considered, 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. The IOTA participant would fulfill its obligation to communicate the required information once a notification was sent, whether by mail, email, or electronically. However, we chose not to propose this alternative because we believe recording only when a notification was sent does not confirm that the information reached the eligible IOTA waitlist beneficiary. We also believe that requiring IOTA participants to document delivery of this notification creates a more accurate medical record, allowing IOTA participants to know with confidence what information eligible IOTA waitlist beneficiaries have in hand when engaging in follow-up discussions or counseling. Furthermore, documenting delivery supports transparency and accountability by demonstrating that IOTA participants are not only generating notices, but also ensuring they arrive, reducing the risk that eligible IOTA waitlist beneficiaries unknowingly miss out on information necessary for shared decision-making. Ultimately, focusing on when it was delivered rather than was sent better serves the purpose of the notification requirement: to keep eligible IOTA waitlist beneficiaries informed and actively engaged in their path to kidney transplantation.

We seek comment on our proposals to provide transparency into kidney transplant organ offers at proposed § 512.442(b). We also seek 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 who are Medicare beneficiaries 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. In the 2024 Final Rule, we stated, in response to comments we received, that we recognized that explaining organ offer filters with waitlisted patients might not promote the same outcome as reviewing organ offer acceptance criteria (*89 FR 96398*). As such, we finalized the transparency requirements at § 512.442(c) with minor technical edits. Specifically, we added ''organ offer'' to transplant acceptance criteria that must be disclosed and removed all references to ''organ offer filter'' from the provision at § 512.442(c). Additionally, at § 512.442(c) we replaced ''selection criteria'' to now say ''acceptance criteria''. We stated that these changes were made in order to clarify the specific provisions regarding the review of transplant organ offer acceptance criteria.

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, we aim 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, we propose 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. We seek comment on our proposal at proposed § 512.442(c) to clarify the meaning of transplant organ offer acceptance criteria. We also seek comment on the proposed definition for

transplant organ offer acceptance criteria at proposed § 512.402.

As described earlier in this section, in the 2024 Final Rule we 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. Additionally, in response to comments we received we stated at *89 FR 96399* that we would provide further sub-regulatory guidance on how IOTA waitlist patients who are Medicare beneficiaries can choose to decline the review of their transplant organ offer acceptance criteria. Since publication, we provided sub-regulatory guidance to IOTA participants in the IOTA Model Newsletter on how IOTA waitlist patients who are Medicare beneficiaries can opt out of this review. However, upon further review of the sub-regulatory guidance we provided to IOTA participants, we realized there was a need to clarify this guidance and account for this requirement when CMS conducts monitoring activities in the IOTA Model.

As such, we propose 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 who are Medicare beneficiaries, IOTA participants must give these beneficiaries an opportunity to decline this review. We propose at § 512.442(c)(1)(ii) that if the IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

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

We also propose that if an IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant would then be required to offer the IOTA waitlist patient who is a Medicare beneficiary the opportunity to review transplant organ offer acceptance criteria once every 6 months at which time the IOTA waitlist patient who is a Medicare beneficiary would have the opportunity to decline this review again. We seek comment on these proposed requirements at proposed § 512.442(c)(1)(i) and (ii).

Lastly, to facilitate compliance monitoring, we propose at § 512.442(c)(2)(i) through (iii) that the IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary's medical record 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.

We seek 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.[62] While awaiting organ transplantation, kidney transplant waitlist patients' status on the waiting list may change between active and inactive multiple times before ultimately receiving a successful transplant. The decision to place a kidney transplant waitlist patient on inactive status can arise from various factors, including hospital admission for vascular access issues, suspected lesions identified during preoperative screening, or poor compliance with dialysis treatments.[63] [64] [65] [66] [67] Any of these concerns may prompt a temporary inactivation until the problem is resolved, allowing for the kidney transplant waitlist patient's reactivation. Barriers to maintaining active status are often multifactorial but frequently modifiable, encompassing symptoms such as fatigue, depression, stress, pain, loss of physical function, social isolation, and decreased health literacy.[68] [69] Inactive status thus indicates a kidney transplant waitlist patient's ineligibility to be considered for organ offers at a given point in time, for many different reasons such as temporarily too sick, temporarily too well, candidate work-up incomplete, etc.[70] [71] [72] [73]

[62] Hart, A., Smith, J.M., Skeans, M.A., Gustafson, S.K., Wilk, A.R., Castro, S., Robinson, A., Wainright, J.L., Snyder, J.J., Kasiske, B.L., & Israni, A.K. (2019). OPTN/SRTR 2017 Annual Data Report: Kidney. *American Journal of Transplantation, 19,* 19–123. *https://doi.org/10.1111/ajt.15274;* The data was retrieved directly from the OPTN website (*https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#*) on April 3, 2025, with the following filters: Category (Waiting List), Count (Candidates), Organ by Status.

[63] Huang, E., Shye, M., Elashoff, D., Mehrnia, A., & Bunnapradist, S. (2014). Incidence of Conversion to Active Waitlist Status Among Temporarily Inactive Obese Renal Transplant Candidates. Transplantation, 98(2), 177–186. *https://doi.org/10.1097/tp.0000000000000037.*

[64] Hladek, M., Curriero, S., Xue, Q.-L., Crews, D., DeMarco, M.M., Wilson, D., Brennan, D., & Szanton, S. (2024). CAPABLE TRANSPLANT: ADAPTATION OF CAPABLE FOR USE WITH OLDER ADULTS WITH INACTIVE STATUS AWAITING KIDNEY TRANSPLANT. *Innovation in Aging, 8*(Supplement_1), 181–181. *https://doi.org/10.1093/geroni/igae098.0585.*

[65] Shafi, S., Zimmerman, B., & Kalil, R. (2012). Temporary Inactive Status on Renal Transplant Waiting List: Causes, Risk Factors, and Outcomes. *Transplantation Proceedings, 44*(5), 1236–1240. *https://doi.org/10.1016/j.transproceed.2012.01.126.*

[66] Tong, A., Hanson, C.S., Chapman, J.R., Halleck, F., Budde, K., Josephson, M.A., & Craig, J.C. (2015). ''Suspended in a paradox''-patient attitudes to wait-listing for kidney transplantation: systematic review and thematic synthesis of qualitative studies. *Transplant International, 28*(7), 771–787. *https://doi.org/10.1111/tri.12575.*

[67] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology:JASN, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[68] Shafi, S., Zimmerman, B., & Kalil, R. (2012). Temporary Inactive Status on Renal Transplant Waiting List: Causes, Risk Factors, and Outcomes. *Transplantation Proceedings, 44*(5), 1236–1240. *https://doi.org/10.1016/j.transproceed.2012.01.126.*

[69] Hladek, M., Curriero, S., Xue, Q.-L., Crews, D., DeMarco, M.M., Wilson, D., Brennan, D., & Szanton, S. (2024). CAPABLE TRANSPLANT: ADAPTATION OF CAPABLE FOR USE WITH OLDER ADULTS WITH INACTIVE STATUS AWAITING KIDNEY TRANSPLANT. *Innovation in Aging, 8*(Supplement_1), 181–181. *https://doi.org/10.1093/geroni/igae098.0585.*

[70] Norman, S.P., Kommareddi, M., & Luan, F.L. (2013). Inactivity on the kidney transplant wait-list is associated with inferior pre- and post-transplant outcomes. *Clinical Transplantation, 27*(4), E435–E441. *https://doi.org/10.1111/ctr.12173.*

[71] Hughes, A., Malhotra, D., Brennan, D., Seldon, L., Carberry, H., Morrison, M., & Hladek, M. (2025). Waitlist management for inactive status kidney transplant patients: a scoping review. *Annals of Medicine & Surgery, 87*(4), 2204–2211. *https://doi.org/10.1097/ms9.0000000000003137.*

Numerous research studies have demonstrated that kidney transplant waitlist patients frequently experience confusion and knowledge deficits regarding the transplant evaluation and listing process.[74] [75] [76] [77] [78] [79] [80] [81] These knowledge gaps often contribute to delays in testing and aborted medical evaluations. Kidney transplant waitlist patients have reported a lack of clarity about their status in the listing process,[82] [83] [84] [85] a belief that they are already on the waiting list,[86] [87] [88] unawareness that tests must be repeated,[89] [90] and misunderstanding about being placed on inactive status on the waiting list.[91] [92] In addition to difficulties navigating the healthcare system, these knowledge deficits can lead to negative perceptions of the transplant process and diminish kidney transplant waitlist patient motivation to complete the required testing. Literature also suggests that kidney transplant waitlist patients who remain in an inactive status for extended periods are less likely to receive a kidney transplant, which is associated with increased waitlist mortality.[93] [94] [95] [96] [97] [98]

Furthermore, 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).[99] [100] 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.

As such, we are proposing to add new requirements at § 512.442(d) for IOTA participants to notify their IOTA waitlist patients who are Medicare beneficiaries when their waitlist status has changed. Specifically, we propose, at § 512.442(d)(1)(i), that IOTA participants must notify their IOTA waitlist patients who are Medicare beneficiaries any time their status on its waitlist is changed that would impact their ability to receive an organ offer (that is, from active to inactive). We seek comment on our proposal to add a change in waitlist transparency requirement at proposed § 512.442(d)(1)(i).

We considered but did not propose requiring IOTA participants to also notify their IOTA waitlist patients who are Medicare beneficiaries whenever

[72] Kataria, A., Gowda, M., Lamphron, B.P., Jalal, K., Venuto, R.C., & Gundroo, A.A. (2019c). The impact of systematic review of status 7 patients on the kidney transplant waitlist. *BMC Nephrology, 20*(1). *https://doi.org/10.1186/s12882-019-1362-6.*

[73] OPTN. (2025). Require Patient Notification for Waitlist Status Changes—OPTN. *Hrsa.gov. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/require-patient-notification-for-waitlist-status-changes/?j=1275952&sfmc_sub=402742420&l=7077_HTML&u=77544833&mid=100001876&jb=2001.*

[74] Kayler, L.K., Dolph, B., Ranahan, M., Keller, M., Cadzow, R., & Feeley, T.H. (2021). Kidney Transplant Evaluation and Listing: Development and Preliminary Evaluation of Multimedia Education for Patients. *Annals of transplantation, 26,* e929839. *https://doi.org/10.12659/AOT.929839.*

[75] Kazley, A.S., Hund, J.J., Simpson, K.N., Chavin, K., & Baliga, P. (2015). Health literacy and kidney transplant outcomes. *Progress in transplantation (Aliso Viejo, Calif.), 25*(1), 85–90. *https://doi.org/10.7182/pit2015463.*

[76] Browne, T., Amamoo, A., Patzer, R.E., Krisher, J., Well, H., Gander, J., & Pastan, S.O. (2016). Everybody needs a cheerleader to get a kidney transplant: a qualitative study of the patient barriers and facilitators to kidney transplantation in the Southeastern United States. *BMC nephrology, 17*(1), 108. *https://doi.org/10.1186/s12882-016-0326-3.*

[77] Kazley, A.S., Simpson, K.N., Chavin, K.D., & Baliga, P. (2012). Barriers facing patients referred for kidney transplant cause loss to follow-up. *Kidney international, 82*(9), 1018–1023. *https://doi.org/10.1038/ki.2012.255.*

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[79] Chisholm-Burns, M.A., Spivey, C.A., & Pickett, L.R. (2018). Health literacy in solid-organ transplantation: a model to improve understanding. Patient Preference and Adherence, 12, 2325–2338. *https://doi.org/10.2147/PPA.S183092.*

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[81] Khalili, M., Cardinal, H., Ballesteros, F., & Fortin, M. (2022). Kidney transplant candidates' and recipients' perspectives on the decision-making process to accept or refuse a deceased donor kidney offer: Trust and graft survival matter. *Clinical Transplantation, 36*(5). *https://doi.org/10.1111/ctr.14604.*

[82] Kazley, A.S., Simpson, K.N., Chavin, K.D., & Baliga, P. (2012). Barriers facing patients referred for kidney transplant cause loss to follow-up. *Kidney international, 82*(9), 1018–1023. *https://doi.org/10.1038/ki.2012.255.*

[83] Kayler, L.K., Dolph, B., Ranahan, M., Keller, M., Cadzow, R., & Feeley, T.H. (2021). Kidney Transplant Evaluation and Listing: Development and Preliminary Evaluation of Multimedia Education for Patients. *Annals of transplantation, 26,* e929839. *https://doi.org/10.12659/AOT.929839.*

[84] Khalili, M., Cardinal, H., Ballesteros, F., & Fortin, M. (2022). Kidney transplant candidates' and recipients' perspectives on the decision-making process to accept or refuse a deceased donor kidney offer: Trust and graft survival matter. *Clinical Transplantation, 36*(5). *https://doi.org/10.1111/ctr.14604.*

[85] Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. *https://stars.library.ucf.edu/etd2020/175/.*

[86] Klassen, A.C., Hall, A.G., Saksvig, B., Curbow, B., & Klassen, D.K. (2002). Relationship between patients' perceptions of disadvantage and discrimination and listing for kidney transplantation. *American journal of public health, 92*(5), 811–817. *https://doi.org/10.2105/ajph.92.5.811.*

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[88] Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. *https://stars.library.ucf.edu/etd2020/175/.*

[89] Trivedi, P., Rosaasen, N., & Mansell, H. (2016). The Health-Care Provider's Perspective of Education Before Kidney Transplantation. *Progress in transplantation (Aliso Viejo, Calif.), 26*(4), 322–327. *https://doi.org/10.1177/1526924816664081.*

[90] Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. *https://stars.library.ucf.edu/etd2020/175/.*

[91] Crenesse-Cozien, N., Dolph, B., Said, M., Feeley, T.H., & Kayler, L.K. (2019). Kidney Transplant Evaluation: Inferences from Qualitative Interviews with African American Patients and their Providers. *Journal of racial and ethnic health disparities, 6*(5), 917–925. *https://doi.org/10.1007/s40615-019-00592-x.*

[92] Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. *https://stars.library.ucf.edu/etd2020/175/.*

[93] Hughes, A., Malhotra, D., Brennan, D., Seldon, L., Carberry, H., Morrison, M., & Hladek, M. (2025). Waitlist management for inactive status kidney transplant patients: a scoping review. *Annals of Medicine & Surgery, 87*(4), 2204–2211. *https://doi.org/10.1097/ms9.0000000000003137.*

[94] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[95] Grams, M.E., Massie, A.B., Schold, J.D., Chen, B.P., & Segev, D.L. (2013). Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. *American Journal of Transplantation, 13*(4), 1012–1018. *https://doi.org/10.1111/ajt.12143.*

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[97] Kulkarni, S., Hall, I., Formica, R., Thiessen, C., Stewart, D., Gan, G., Greene, E., & Deng, Y. (2017). Transition probabilities between changing sensitization levels, waitlist activity status and competing-risk kidney transplant outcomes using multi-state modeling. *PLoS ONE, 12*(12), e0190277–e0190277. *https://doi.org/10.1371/journal.pone.0190277.*

[98] Kataria, A., Gowda, M., Lamphron, B.P., Jalal, K., Venuto, R.C., & Gundroo, A.A. (2019b). The impact of systematic review of status 7 patients on the kidney transplant waitlist. *BMC Nephrology, 20*(1). *https://doi.org/10.1186/s12882-019-1362-6.*

[99] UNOS Transplant Living. (n.d.). *The kidney transplant waitlist.* UNOS Transplant Living. Retrieved April 5, 2025, from *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[100] While there is currently no requirement for transplant hospitals to inform patients on its waitlist when there is a change in waitlist status, we acknowledge that the OPTN has recently proposed such a policy.

their status changes from inactive to active in addition to whenever their waitlist status changes from active to inactive. We believe this alternative considered would ensure that IOTA waitlist patients who are Medicare beneficiaries are immediately informed when they regain eligibility to receive organ offers, which is critical for their potential access to life-saving transplantation, while enhancing beneficiary engagement through transparency about significant changes in transplant eligibility status and guaranteeing consistent, timely information across all IOTA participants. However, we recognize that requiring such notifications could impose significant administrative burden on IOTA participants, particularly IOTA participants with limited resources, requiring substantial investments in new systems and staff time that could divert resources from direct patient care. Additionally, frequent status change notifications might create patient anxiety and unrealistic expectations about organ offer immediacy, potentially overwhelming clinical teams and undermining transparency goals, while standardized requirements may fail to account for diverse patient populations with varying literacy levels and communication needs. While we are not proposing to also require IOTA participants to notify their IOTA waitlist patients who are Medicare beneficiaries whenever their status from inactive to active, we are seeking public comment regarding whether the inclusion of a notification whenever their waitlist status changes from inactive to active in addition to whenever their waitlist status changes from active to inactive would be preferable and would not impose additional administrative burden upon IOTA participants.

We propose at § 512.442(d)(1)(ii) that IOTA participants must include all of the following in this notification to IOTA waitlist patients who are Medicare beneficiaries:

The most recent date the IOTA waitlist patient who is a Medicare beneficiary became inactive.

- The reason for the change in waitlist status.
- That the IOTA waitlist patient who is a Medicare beneficiary cannot receive organ offers while inactive.
- Information on how the IOTA waitlist patient who is a Medicare beneficiary 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 who is a Medicare beneficiary may contact the IOTA participant for more information or with any questions.

We seek public comment on our proposed change in waitlist status notification requirements at proposed § 512.442(d)(1)(ii). In addition, we are also interested in comments on whether the proposed information to include in the change in waitlist status notification should include additional information.

We propose at § 512.442(d)(1)(iii) that IOTA participants must provide this notification to the IOTA waitlist patient who is a Medicare beneficiary—

- Electronically or by mail;
- Within 10 days of the IOTA waitlist patient who is a Medicare beneficiary'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).

We considered alternative methodologies for implementing this provision. For example, we 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, as described in section II.B.4.a(3) of this proposed rule. However, we believe that this proposed requirement would impose less administrative burden on IOTA participants than the proposed transparency into kidney transplant organ offers requirement to share information about declined kidney transplant organ offers, as described in section II.B.4.a(3) of this proposed rule, and could be implemented at an earlier stage.

We also considered alternative timelines for continued notification that an IOTA waitlist patient who is a Medicare beneficiary remains inactive on an IOTA participants waitlist, such as every 60 days, 90 days, or 180 days, but proposed an annual update based on an attempt to balance utility to the beneficiary with burden on the IOTA participants. We further considered alternative timelines not predicated on consecutive days but instead based on inactive status for at least 75 percent or 90 percent of days during a specified timeline, rather than reaching 365 consecutive days. We additionally considered an alternative timeline structured around the point at which an IOTA waitlist patient who is a Medicare beneficiary is ultimately discharged from a hospital. We also considered requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries about internal holds; however, we were uncertain regarding the implementation methodology for this provision.

We seek public comment on our proposed change in waitlist status delivery method and timeline requirements at proposed § 512.442(d)(1)(iii)). We also seek comment on the alternatives considered.

We also propose at § 512.442(d)(2) that the IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary medical record all of the following:

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

Additionally, we propose at § 512.442(d)(3) that for IOTA waitlist patients who are Medicare beneficiaries 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,[101] the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient who is a Medicare beneficiary.

This notification timeframe conforms with the current timeframe at *§ 482.94,* however, we solicit public comment on alternative timeframes that may be appropriate. We expect that IOTA participants would be expeditious and deliberate in determining an IOTA waitlist patient who is a Medicare beneficiary's waitlist status and communicating that information to them, the OPTN, and others as appropriate. We propose to finalize these requirements only if they are not redundant with other HHS guidance.

We seek public comment on these proposed documentation requirements at proposed § 512.442(d)(2) through (3).

We understand that a kidney transplant waitlist patient's condition or situation may change over time and warrant kidney transplant hospitals reassessing the kidney transplant waitlist patient to determine if their waitlist status should be updated.

[101] A Non-ESRD patient is someone who has healthy kidneys or chronic kidney disease (CKD) in a less severe form that does not constitute irreversible kidney failure. These patients do not require life-sustaining dialysis treatment or an immediate kidney transplant, and their condition is managed through other medical treatments. However, non-ESRD patients may still be eligible to get wait listed for a preemptive kidney transplant before their kidney function deteriorates to the point of requiring dialysis.

However, we believe kidney transplant waitlist patients should be aware of these situations and the impact it has on their ability to receive an offer. Additionally, we also believe that ''internal holds,'' which are a process used by the kidney transplant hospital to temporarily not consider offers for a kidney transplant waitlist patient, despite the kidney transplant waitlist patient being listed as active with the OPTN are detrimental to the efficiency of the organ allocation system and could lead to increased organ discards by slowing down the allocation process. At present, there are no national policies mandating that kidney transplant waitlist patients be notified when they are designated as inactive, whether due to patient-specific reasons or after an extended period of inactivity. We believe that this proposed requirement would establish consistency across all IOTA participants in informing IOTA waitlist patients who are Medicare beneficiaries about their inactive waitlist status and are unable to receive organ offers. As such, we believe that these IOTA waitlist patients who are Medicare beneficiaries would gain greater awareness of their listing status and the necessary steps to become eligible to receive an organ for transplant.

Furthermore, we believe that the proposals in this section would improve communication between IOTA participants and their IOTA waitlist patients who are Medicare beneficiaries regarding their waitlist status and the implications of being inactive on a waitlist. Although these proposed requirements could create additional work for transplant coordinators in particular, we believe that they would promote effective and safe care for persons with organ failure by increasing IOTA waitlist patients who are Medicare beneficiaries' awareness of their inactive waitlist status and provide them with the information required to be proactive in their reactivation. We note that the intent of these notifications is to prevent IOTA waitlist patients who are Medicare beneficiaries from being inactive on a waitlist for unnecessarily extended period of times.

b. Health Equity Plans

In the 2024 Final Rule (*89 FR 96407*), in response to comments,[102] we finalized at *§ 512.446(a)* that an IOTA participant may voluntarily submit a health equity plan for all performance years (PY 1 through PY 6) and in a form and manner and by the date(s) specified by CMS. We also finalized that a health equity plan voluntarily submitted by an IOTA participant must include all elements at § *512.446(a)(1)* through *(7).* We direct readers to the 2024 Final Rule for a full discussion of this policy, our rationale for this approach, and alternatives considered (*89 FR 96405* through *96407*). Lastly, we proposed and finalized the definitions for ''Health equity goal'', ''Health equity plan'', ''Health equity plan intervention strategy'', and ''Health equity plan performance measure'' at *§ 512.402.*

We continue to maintain that understanding and addressing the health needs of all IOTA waitlist patients and IOTA transplant patients remains essential to ensuring their benefit through improved access to the transplantation ecosystem. However, in consideration of the current Administration's priorities and concerns regarding the imposition of additional burden on IOTA participants within a mandatory model, we propose removing the voluntary health equity plan provisions from the IOTA Model. We recognize that requesting IOTA participants to submit health equity plans, even on a voluntary basis, could impose an additional burden on IOTA participants. As such, we believe removing the voluntary health equity plan provisions from the IOTA Model would reduce burden on IOTA participants and constitute a more effective utilization of IOTA participant resources to focus on increasing access to kidney transplants, which would enhance their performance within the model and improve the quality of care.

Therefore, in this proposed rule we are proposing to remove the health equity plan provisions from § 512.446 (a)(1) through (7). Though currently there is no replacement for these policies, CMS may consider adding elements that are consistent with the current Administration's focus on Making America Healthy Again (MAHA) through future notice and comment rule making. We believe there is an opportunity through IOTA Model to drive improvements in overall health by increasing access to kidney transplants. Lastly, given that we are proposing to remove all healthy equity provisions at § 512.446, we propose removing the definitions for health equity goal, health equity plan, health equity plan intervention strategy, and health equity plan performance measure at *§ 512.402.* We are proposing to remove all health equity plan provisions at § 512.446 to reduce burdensome requirements on IOTA participants to allow IOTA participants to focus their resources on the core objective of the model, increasing access to kidney transplants, as well as to comply with Executive Order 14151 Ending Radical and Wasteful Government DEI Programs and Preferencing (*90 FR 8339*) [103] issued January 20, 2025. CMS also wants to reiterate that allocation and transplantation decisions should be made based on objective and measurable medical criteria through the framework set up by the OPTN under *42 CFR 121.8* and should not be made on the basis of race or other criteria not laid out by the goals described in this section of the CFR.

We seek comment on our proposal to remove health equity plans from the IOTA Model and remove the corresponding regulations at § 512.446. We also seek comment on our 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.

5. Beneficiary Protections

a. Background

In the 2024 Final Rule (*89 FR 96413*), we finalized that IOTA participants must provide notice to attributed patients that they are participating in the IOTA Model as described in *§ 512.450(a)(1).* However, CMS only has the authority to place requirements upon notifications to Medicare beneficiaries. As such, this notice should have been limited to Medicare beneficiaries. Therefore, we propose to update the policy at § 512.450(a)(1) to limit these notification requirements to Medicare beneficiaries only.

We seek comment on our proposal at proposed § 512.450(a)(1) to limit the notification requirement to Medicare beneficiaries.

b. Beneficiary Notifications

In the 2024 Final Rule (*89 FR 96413*), we finalized that in order to notify attributed patients of their rights and protections, and that the IOTA participant is participating in the IOTA

[102] Commenters provided mixed opinions to the proposed health equity plan provisions, with approximately 70 percent expressing concern that it would be an unfunded administrative burden and would have unintended consequences. Approximately 10–15 percent of commenters expressed clear support and 15–20 percent of commenters neither clearly supported nor opposed but offered suggestions for improvement.

[103] Ending Radical And Wasteful Government DEI Programs And Preferencing: *https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-and-wasteful-government-dei-programs-and-preferencing/.*

Model, the IOTA participant needed to provide an approved beneficiary notification template to each attributed patient in a paper format as described in *§ 512.450(a)(3)(iii).*

Since then, we have received feedback from IOTA participants that the main form of communication with their patients is through electronic means, often a patient portal where the patients receive all communication from the IOTA participant. We propose at § 512.450(a)(3)(iii)(A) and (B) allowing IOTA participants to distribute the paper copy of this notification to applicable attributed patients at their first office visit or other outpatient visit with the attributed patient after the start of the Model or, if the attributed patient has affirmatively opted out of receiving paper communication and has chosen to receive communication through electronic methods, this notification can be distributed through that agreed upon electronic method.

We seek comment on our 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.

6. Monitoring

In the 2024 Final Rule (*89 FR 96430*), we finalized a list of monitoring activities to ensure compliance and promote the safety of attributed patients and the integrity of the IOTA Model as described in *§ 512.462(b)(2).* Monitoring activities include documentation requests including surveys and questionnaires, audits of claims data, quality measures, medical records, interviews, site visits, monitoring attributed patient engagement incentives, monitoring out of sequence allocation, etc. However, we inadvertently omitted monitoring of the transparency requirements specified in § 512.442. These include:

- Publicly posting selection criteria in accordance with § 512.442(a);
- Informing eligible IOTA waitlist beneficiaries, 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 who are Medicare beneficiaries 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 who are Medicare beneficiaries when their waitlist status has changed from active to inactive in accordance with proposed § 512.442(d). Therefore, we propose 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.

We seek comment on these proposed requirements at proposed § 512.462(b)(2)(xi), (xii), (xiii), and (xiv).

7. Remedial Action and Termination

In the 2024 Final Rule (*89 FR 96433*), we finalized a list of reasons why CMS may immediately or with advance notice terminate an IOTA participant from the IOTA Model as described in *§ 512.466.* For example, CMS may immediately or with advance notice terminate an IOTA participant from participation in the model if due to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency, or if an IOTA participant is subject to investigation or action by HHS (including Office of Inspector General (OIG) and CMS) or the Department of Justice (DOJ) due to an allegation of fraud or significant misconduct.

However, we unintentionally omitted HHS and the OPTN as sources of vital information regarding possible events by IOTA participants identified as presenting a risk to patient safety, public health, etc., that may lead CMS to terminate IOTA participants. Therefore, we propose at § 512.466(a)(3)(ix)(C) to include a provision that states CMS can 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,[104] OPTN's Management and Membership policies,[105] or HHS's regulation (*42 CFR 121*) upon a review conducted pursuant to 42 CFR 121.10. We also propose the following minor technical changes to account for our proposal at § 512.466(a)(3)(ix)(C):

- Remove the following verbiage from § 512.466(a)(3)(ix)(A): or
- Add the following punctuation and verbiage at the end of § 512.466(a)(3)(ix)(B): or

We seek comment on our 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. We also seek comment on our minor technical corrections at proposed § 512.466(a)(3)(ix)(A) and (B).

C. Request for Information (RFIs) on Topics Relevant to the IOTA Model

This section includes several requests for information (RFIs). In responding to the RFIs, the public is encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and would not accept unsolicited proposals. Respondents are advised that the U.S. Government would not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs would be solely at the respondent's expense. Failing to respond to any of the RFIs would not preclude participation in any future procurement, if conducted.

Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual respondents. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and would not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Pre-Transplantation Access Process Measure

In the 2024 Final Rule (*89 FR 96346*), we 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 transplant, such as in who is referred and placed on the waiting list, who remains ''active'' on the waiting

[104] For current OPTN policies please see *https://optn.transplant.hrsa.gov/policies-bylaws/policies/.*

[105] For current OPTN Membership and Management Policies please see *https://optn.transplant.hrsa.gov/policies-bylaws/optn-management-and-membership-policies/.*

list, and how waitlisted patients are managed by kidney transplant hospitals.[106] Studies have shown long-standing barriers and disparities to access to transplantation by patient demographics, such as socioeconomic and insurance factors. Disparities are driven by various factors, but we recognize that delays or lack of referrals for evaluation, evaluation criteria that may unintentionally deem a patient not eligible to be placed on a waitlist, and organ acceptance rate variations across kidney transplant hospitals, may exacerbate disparities.[107] [108] [109] [110] Additionally, kidney transplant hospital performance is commonly measured by post-transplant outcomes.

The absence of standardized national criteria for transplant eligibility and post-transplant outcome regulations has led to inconsistent patient selection and waitlisting practices among transplant hospitals.[111] [112] All kidney transplant waitlist patients, regardless of whether they receive organs from living or deceased donors, must be placed on the kidney transplant waitlist. 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.

An outcome or process measure for a transplant waitlist refers to a metric used to evaluate the efficiency and effectiveness of how a transplant hospital manages its waitlist, including factors like patient evaluation time, waitlist activation time, communication with patients, adherence to listing criteria, and timely organ offer acceptance, all aimed at optimizing the waitlist experience for transplant candidates and maximizing organ utilization. We recognize that including pre-transplant process measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making.[113] [114] 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.

We are seeking public comments on the following questions. We encourage 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 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)?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform any future quality measure efforts, as appropriate.

2. Allocation Out-of-Sequence (AOOS)

In the 2024 Final Rule (*89 FR 96429*), we discussed our concerns around the issue of AOOS transplants. As we stated in the 2024 Final Rule at *89 FR 96429:* CMS is concerned about IOTA participants bypassing the match run, as defined in section III.C.5.d(1)(a) of [the] final rule, 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. We proposed that CMS would monitor out of sequence allocation of kidneys by assessing how often an organ is offered or accepted for a transplant candidate or potential transplant recipient that deviates from the match sequence.

As a result, we 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

[106] 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.*

[107] Boerstra, B.A., Pippias, M., Kramer, A., Dirix, M., Daams, J., Jager, K.J., Hellemans, R., & Stel, V.S. (2024). The evaluation of kidney transplant candidates prior to waitlisting: a scoping review. *Clinical Kidney Journal, 18*(1). *https://doi.org/10.1093/ckj/sfae377.*

[108] Patzer, R.E., Perryman, J.P., Schrager, J.D., Pastan, S., Amaral, S., Gazmararian, J.A., Klein, M., Kutner, N., & McClellan, W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation, 12*(2), 358–368. *https://doi.org/10.1111/j.1600-6143.2011.03927.x.*

[109] Husain, S.A., Yu, M.E., King, K.L., Adler, J.T., Schold, J.D., & Mohan, S. (2023). Disparities in kidney transplant waitlisting among young patients without medical comorbidities. *JAMA Internal Medicine, 183*(11), 1238. *https://doi.org/10.1001/jamainternmed.2023.5013.*

[110] Harding, J.L., Perez, A., Snow, K., Retzloff, S., Urbanski, M., White, M.S., & Patzer, R.E. (2021). Non-medical barriers in access to early steps of kidney transplantation in the United States—A scoping review. *Transplantation Reviews, 35*(4), 100654. *https://doi.org/10.1016/j.trre.2021.100654.*

[111] Schold, J.D., Buccini, L.D., Poggio, E.D., Flechner, S.M., & Goldfarb, D.A. (2016). Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight. *American Journal of Transplantation, 16*(4), 1276–1284. *https://doi.org/10.1111/ajt.13594;* Schold, J.D., Arrigain, S., Flechner, S.M., Augustine, J.J., Sedor, J.R., Wee, A., Goldfarb, D.A., & Poggio, E.D. (2018). Dramatic secular changes in prognosis for kidney transplant candidates in the United States. *American Journal of Transplantation, 19*(2), 414–424. *https://doi.org/10.1111/ajt.15021;* Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277.*

[112] Caldwell, J.S., Cheng, X.S., Chertow, G.M., & Goldhaber-Fiebert, J.D. (2025). Kidney transplant wait times under waiting list expansion scenarios. *JAMA Network Open, 8*(3), e251665. *https://doi.org/10.1001/jamanetworkopen.2025.1665.*

[113] Nishio, A.G., Patel, A., Mehta, S., Yadav, A., Doshi, M., Urbanski, M.A., Concepcion, B.P., Singh, N., Sanders, M.L., Basu, A., Harding, J.L., Rossi, A., Adebiyi, O.O., Samaniego-Picota, M., Woodside, K.J., & Parsons, R.F. (2024). Expanding the access to kidney transplantation: Strategies for kidney transplant programs. *Clinical Transplantation., 38*(5). *https://doi.org/10.1111/ctr.15315.*

[114] Yeung, M.Y., Coates, P.T., & Li, P.K. (2022). Kidney Organ Allocation System: How to Be Fair. *Seminars in Nephrology, 42*(4), 151274. *https://doi.org/10.1016/j.semnephrol.2022.09.002.*

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 our 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. In that letter,[115] 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.[116]

In response to the 2024 Proposed Rule, we received numerous comments from the public worried about the impact of the IOTA Model on further promoting AOOS. In the 2024 Final Rule (*89 FR 96347*), we saw comments around the efficiency metric where a commenter was concerned that out-of-sequence kidney offers are included in the measurement of success. Similarly, another commenter suggested CMS monitor the rate of AOOS that occurs. Another commenter was also worried that the IOTA Model, as proposed, could lead to an increase in AOOS to prioritize deceased donor kidney transplants (DDKTs) for its aligned population to increase scoring in the achievement domain.

While we 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, we are seeking public 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 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 our monitoring efforts laid out in § 512.462(b)(2)(x), we plan to monitor AOOS. What considerations or stratifications should CMS take into account when monitoring AOOS?''

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform any future quality measure or CMS policy efforts.

III. Collection of Information Requirements

CMS Innovation Center Models including the Increasing Organ Transplant Access (IOTA) Model are implemented and tested under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, *Chapter 35 of title 44, United States Code,* shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule would need not to be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Statement of Need

The IOTA Model is a 6-year mandatory Medicare payment model operated by the CMS Innovation Center that tests whether upside and downside performance-based payments (''upside risk payments'' and ''downside risk payments'') increase the number of kidney transplants performed by IOTA participants (that is, kidney transplant hospitals).

This proposed rule proposes to update the composite graft survival rate calculation and scoring methodology.

Under this proposed rule, model payments would be based on the number of transplant recipients who are beneficiaries with Medicare FFS coverage including beneficiaries with Medicare as a secondary payer.

Under the current specifications in the 2024 Final Rule, points earned in the quality domain are based on the IOTA participants' performance on the composite graft survival rate metric relative to national ranking, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. In response to public comment concerns about the proposed points allocation for the composite graft survival rate, arguing that it unfairly penalizes kidney transplant hospitals that accept higher-risk kidney transplant patients and suggesting modifications including lowering the threshold for maximum points over the lack of risk-adjustment on the composite graft survival rate, this proposed rule includes a modified points allocation. In this proposed rule, the modifications to the allocation of points awarded to IOTA participants for the composite graft survival rate would remove the possibility of getting free points for poor performance and provide a more even scoring distribution for participants.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts.). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or

[116] *https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/allocation-out-of-sequence-aoos/.*

communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1) of E.O. 12866. Although we do not come close to the threshold to be considered significant under section 3(f)(1), we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

C. Detailed Economic Analysis

1. Revised Baseline

In this proposed rule, the baseline projection from the 2024 Final Rule was revised to include updated projections regarding the declining share of beneficiaries in Medicare FFS versus MA currently expected over the course of the model. To isolate the impact of the updated projections of the share of beneficiaries in Medicare FFS versus MA, no changes in this proposed rule are included in the revised baseline impact displayed in Table 4. Reducing the share of transplants estimated to be eligible for the incentive reduces the baseline expected number of added transplants by nearly 10 percent, which is roughly offset by the expected associated decrease in incentive payments due to fewer overall transplants. As a result, the net impact is virtually unchanged at $29 million over 6 years (see Table 4) from $28 million estimated in the 2024 Final Rule.

TABLE 4: RESTATED BASELINE IMPACT ON UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING (PRESUMES NO CHANGES TO THE MODEL FROM 2024 FINAL RULE)

							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	13	15	17	19	19	20	104	81	127
Downside Risk Payments	0	0	0	0	0	0	-1	-2	-1
Total Net Payments	13	15	17	19	19	20	103	80	126
Added Transplants	149	316	503	702	842	884	3,396	1,242	5,846
Impact on Federal Spending	-5	-11	-18	-27	-34	-37	-132	-140	-36
Mean Net Savings	8	4	-1	-8	-15	-17	-29	-140	68

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions.

2. Modification of Scoring on Composite Graft Survival Rate

In the 2024 Final Rule, points earned in the quality domain are based on the IOTA participants' performance on the composite graft survival rate metric relative to national ranking, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. Currently, points are awarded to the IOTA participant for their composite graft survival rate as described in Table 5.

TABLE 5: CURRENT COMPOSITE GRAFT SURVIVAL RATE SCORING: 2024 FINAL RULE

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

In response to public comment concerns about the proposed points allocation for the composite graft survival rate, arguing that it unfairly penalizes kidney transplant hospitals that accept higher-risk kidney transplant patients and suggesting modifications including lowering the threshold for maximum points over the lack of risk adjustment on the composite graft survival rate, a modified points allocation is proposed in Table 6. This proposed scoring would remove the possibility of getting free points for poor performance and provide a more even scoring distribution for participants.

TABLE 6: 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

4. Projected Impact

Table 7 shows the projected impacts for upside and downside risk payments, transplants, and Federal spending. Although transplant recipients with any type of insurance may benefit from a kidney transplant hospital's participation in the model, model payments in this proposed rule are based on the number of transplant recipients who are beneficiaries with Medicare FFS coverage including beneficiaries with Medicare as a secondary payer. Roughly 26 percent of IOTA participants are projected to receive upside risk payments in the first year, rising to about 32 percent over the succeeding 5 model years, with fewer than 26 percent of IOTA participants projected to owe downside risk payments in any of PYs 3 through 6. The magnitude of the average downside risk payment is relatively small, and the cumulative projected upside risk payments to IOTA participants, amounting to $76 million, are nearly 25 times the magnitude of a cumulative $3 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new kidney transplants was greater than the net cost of payments in about 85 percent of simulation trials. Overall, mean net savings totaled $50 million over 6 years, ranging from a savings of $153 million to a cost of $39 million at the 10th and 90th percentiles.

TABLE 7: PROJECTED IMPACT OF UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING

							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	9	11	13	15	13	14	76	57	95
Downside Risk Payments	0	-1	-1	-1	-1	-1	-3	-4	-2
Total Net Payments	9	11	13	14	12	14	73	54	92
Added Transplants	137	292	464	646	772	811	3,123	1,188	5,236
Impact on Federal Spending	-5	-10	-17	-25	-31	-34	-123	-153	-34
Mean Net Savings	5	1	-4	-11	-19	-21	-50	-153	39

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions.

In Table 7, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. The mean net savings results were generated from the average of 10,000 individual simulation trials and the results for the percentiles are from the top 10th and 90th percentiles of the 10,000 individual simulations. The outcomes in each row do not necessarily flow from the same trial in the model at the 10th and 90th percentiles. For example, the 90th percentile for added transplants more likely corresponds to the trial that produced the 10th percentile in impact on Federal spending from those kidney transplants (because spending is reduced when kidney transplants grow).

5. Net Impact of Proposed Changes (Proposed Model Impacts Less Revised Baseline)

In Table 8, we show the impact of the proposed changes on projected model outcomes, given by taking the proposed impacts in Table 7 less the revised baseline impacts in Table 4. 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

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions.

6. Estimated Burden on Kidney Transplant Hospitals

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 (that is, kidney transplant hospitals). To estimate the compliance cost we focused on § 512.442(c) that requires IOTA participants to review organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries at least every 6 months that the Medicare beneficiary is on their waitlist. For this estimate, we assume that the IOTA participant will take a total of 15 minutes per patient per year to review the criteria at least twice a year with each patient. This assumption likely yields an upper estimate since the method (for example, patient visit, phone, email, or mail) of how the IOTA participant communicates the review with the IOTA waitlist patient who is a Medicare beneficiary is up to the IOTA participant and will likely vary by IOTA participant, potentially reducing the time to conduct the review. In addition, the IOTA waitlist patient who is a Medicare beneficiary may decline the review, resulting in the IOTA participant having fewer Medicare waitlist patients than what is used in our estimate.

We estimate that the average IOTA participant would have 200 waitlist patients who are Medicare primary payer or Medicare secondary payer beneficiaries per year and that it would take a clinician 15 minutes to review organ offer acceptance criteria with each patient each year. Using base wage information from the Bureau Labor of Statistics (BLS) for a nurse practitioner (series 29–1171), we estimate the cost of completing these reviews to be $63.46 per hour.[117] The base wage is then doubled [$63.46 × 2] to account for fringe benefits and overhead to equal an estimated cost of $126.92 per hour.[118] The cost of completing these reviews would then be $6,346.00 per kidney transplant hospital per year [200 Medicare IOTA waitlist patients × 0.25 hour per review each year × $126.92 hourly wage]. We also estimate that 25 percent of beneficiaries would need to notified each year of a declined offer, and a further 25 percent would need to be notified of a change in waitlist status. Using the same wage assumption noted previously, this would add $3,173 in cost per hospital [100 Medicare IOTA waitlist patients requiring either type of notification × 0.25 hour per notification × $126.92 hourly wage]. Total estimated hospital cost per year is $9,519 per year [$6,346 + $3,173]. Therefore, 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 [$9,519.00 × 103 IOTA participants = $980,457.00]. The average total revenue for IOTA participants was calculated from inpatient claims with DRGs 008, 019, 650, 651, or 652 submitted for adult Medicare FFS or MA beneficiaries with Medicare as their primary or secondary payer was estimated to be $2 million in calendar year (CY) 2024. Therefore, the $9,519.00 cost per IOTA participant to review the organ offer acceptance criteria would represent 0.5 percent [$9,519.00/$2,000,000 = 0.5%] of their estimated total annual revenue from kidney transplants for Medicare beneficiaries.

7. Alternatives Considered

We considered an alternative policy that would both (a) include Medicare Advantage (MA) beneficiaries 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. At baseline, the growth of MA enrollment in the ESRD population presents a risk that counterproductive incentives could effectively increase barriers to transplantation in the CKD population. Transplant-eligible beneficiaries represent the healthiest (and potentially most profitable) ESRD enrollment subset for the average MA plan, particularly as the marginal increase in premium from each additional diagnosis code submitted by the plan is significantly higher when the payment is calculated relative to the base ESRD rate (roughly $10,000 PBPM) as opposed to the aged/disabled base rate (currently about $1,200 PBPM) which would otherwise become effective in months following transplant with a functioning graft. In addition to the reducing monthly premium to MA plans (including their returns on coding intensity initiatives), transplantation for the non-aged ESRD population could be further disincentivized in MA because it generally leads to the end of Medicare eligibility, and as noted before, plans would financially benefit from keeping healthier transplant-eligible beneficiaries enrolled for as long as possible at the higher base payment rate.

MA now enrolls more than half of ESRD beneficiaries and is projected to eclipse 60 percent penetration during the model testing period. We also estimate that federal savings would be marginally greater for the average additional transplant under MA because risk scores tend to over-project ESRD spending for beneficiaries meeting the

[117] Bureau of Labor Statistics (BLS). May 2024. ''Occupational Employment and Wage Statistics.'' Accessed on June 9, 2025. *https://www.bls.gov/oes/current/oes_nat.htm.*

[118] Guidelines for the adjustment in base wages is based on the following report: Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2017. ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

clinical criteria for transplantation. An analysis of Hierarchical Condition Category (HCC) risk score and Medicare Part A and B spending data for a cohort of 1,450 transplanted Medicare FFS primary payer beneficiaries from the first quarter of 2023 indicated actual spending of only $4,782 PBPM compared to $6,935 in average estimated monthly MA premium had the beneficiary been enrolled in Medicare Part C during the 9-month period preceding transplant. Table 7 shows the total beneficiary months, total actual spending, and total predicted MA payment from this sample, where MA payment was estimated by multiplying average monthly HCC risk scores by the corresponding 2023 FFS USPCC from the 2025 Announcement.[119]

TABLE 9: COMPARISON OF PRE-TRANSPLANT COHORT ACTUAL SPENDING (9-MONTH PERIOD PRIOR TO TRANSPLANT) TO PROJECTED MA PREMIUM BASED ON ACTUAL HCC RISK SCORES

	Months in Sample	Actual Spending	Predicted MA Payment
Cohort Totals	11,453	$54,772,787	$79,432,166
Per Beneficiary Per Month (PBPM)		$4,782	$6,935

On the other hand, after about 2 years post-transplant, cumulative post-graft spending appeared virtually identical to what the premium spending would have projected to be according to actual post-graft HCC scores. Assuming 45 percent of new transplants generated by the model are for MA beneficiaries, and these marginally added savings of $2,000 PBPM accrue for what would have been on average 6-months of obviated MA ESRD enrollment, mean savings per added transplant would be assumed to grow by about $5,000 relative to the $40,000 average savings assumed under the policies in this rule which exclude MA beneficiaries from triggering model incentives.

Table 10 shows the projected impacts for upside and downside risk payments, transplants, and Federal spending under the alternative considered where the model would include beneficiaries with Medicare FFS or MA coverage including beneficiaries with Medicare as a secondary payer. Under this alternative, roughly 27 percent of IOTA participants would be projected to receive upside risk payments in the first year, rising to about 34 percent over the succeeding 5 model years, with fewer than 25 percent of IOTA participants projected to owe downside risk payments in any of PYs 3 through 6. The magnitude of the average downside risk payment would be relatively small, and the cumulative projected upside risk payments to IOTA participants, amounting to $79 million, would be nearly 20 times the magnitude of a cumulative $4 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new kidney transplants was greater than the net cost of payments in about 85 percent of simulation trials. Overall under this alternative, mean net savings would be expected to total $98 million over 6 years ($48 million greater than the proposed model estimated in Table 7), ranging from a savings of $228 million to a cost of $14 million at the 10th and 90th percentiles.

TABLE 10: PROJECTED IMPACT OF PROPOSED RULE ALTERNATIVE CHANGES: ALTERNATIVE POLICY UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING

							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	10	12	14	15	14	15	79	60	98
Downside Risk Payments	0	-1	-1	-1	-1	-1	-4	-5	-3
Total Net Payments	10	11	13	14	13	14	74	55	94
Added Transplants	165	351	558	780	933	980	3,767	1,415	6,352
Impact on Federal Spending	-6	-14	-24	-35	-44	-48	-172	-228	-59
Mean Net Savings	3	-4	-11	-21	-31	-34	-98	-228	14

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions. Whereas this alternative includes savings for MA beneficiary transplants, the proposed policy estimates in tables 7 and 8 do not presume any impact on the MA population.

In Table 10, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. The mean net savings results were generated from the average of 10,000 individual simulation trials and the results for the percentiles are from the top 10th and 90th percentiles of the 10,000 individual simulations. The outcomes in each row do not necessarily flow from the same trial in the model at the 10th and 90th percentiles. For example, the 90th percentile for added transplants more likely corresponds to the trial that produced the 10th percentile in impact on Federal spending from those kidney transplants (because spending is reduced when kidney transplants grow).

In Table 11, we show the impact of the proposed changes on projected

[119] See pages 15 and 16 in the announcement accessible at *http://www.cms.gov/files/document/2025-announcement.pdf*.

model outcomes, given by taking the proposed impacts in Table 10 less the revised baseline impacts in Table 4. 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 ALTERNATIVE 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

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions. Whereas this alternative includes savings for MA beneficiary transplants, the proposed policy estimates in tables 7 and 8 do not presume any impact on the MA population.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the 160 total unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

We estimate the time it will take for a medical and health services manager to review the proposed rule to be 1 hour [30,000 words × 50 percent read through ÷ 250 words per minute ÷ 60 minutes = 1 hour]. Using the wage information from BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $132.44 per hour, including overhead and fringe benefits [$66.22 mean hourly wage × 2 = $132.44].[120] The cost of reviewing the rule for each commenter would be $132.44 [1 hour to review the rule × $132.44 per hour = $132.44] or a total cost of $21,190.40 [$132.44 × 160 unique commenters = $21,190.40].

Assuming that not all commenters will be IOTA participants and to put the cost of the regulatory review for kidney transplant hospitals in context, we calculate the cost of reviewing the rule separately for the IOTA participants. The cost of reviewing the rule for each IOTA participant would be $132.44 [1 hour to review the rule × $132.44 per hour = $132.44] or a total cost of $13,641.32 [$132.44 × 103 IOTA participants = $13,641.32]. Therefore, the $132.44 cost per IOTA participant to complete the regulatory review would represent approximately 0.007 percent [$132.44/$2,000,000 = 0.3%] of their estimated total annual revenue from kidney transplants for Medicare beneficiaries.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at *https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 12 showing the classification of the impact associated with the provisions of this proposed rule. Annualized estimates were determined from Table 8 Mean Net Savings, and the 10th and 90th percentiles from the same table for determining the minimum and maximum estimates. Not reported in Table 12 is the estimated total cost of the regulatory review which is a one-time total cost of $34,831.72. This includes the cost of reviewing the proposed rule for all commenters ($21,190.40) plus the cost of reviewing the rule for the IOTA participants ($13,641.32). These costs were not included in Table 8 because the total amount is so small that if we were to annualize it over the projection period then the result would be too small to report.

[120] Bureau of Labor Statistics (BLS). May 2024. ''Occupational Employment and Wage Statistics.'' Accessed on June 9, 2025. *https://www.bls.gov/oes/current/oes_nat.htm.*

[121] Estimated annualized monetized transfers round to the same values shown in the table regardless of choosing a discount rate of 3 percent or 7 percent.

TABLE 12: ACCOUNTING STATEMENT

Category	*Primary Estimate*	*Minimum Estimate*	*Maximum Estimate*	*Source Citation (RIA, preamble, etc.)*
BENEFITS				
Annualized monetized benefits				
Annualized quantified, but unmonetized, benefits				
Qualitative (unquantified) benefits				
COSTS				
Annualized monetized costs	See comment in Section E. Accounting Statement and Table			Section D. Regulatory Review Cost Estimation
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget" [121]	-$3 million	-$5 million	-$2 million	RIA Table 8
From whom to whom?	From CMS to IOTA participants			
Annualized monetized transfers: "on budget"				
From whom to whom?				

G. Regulatory Flexibility Act (RFA)

Effects on IOTA participants in the model include the potential for additional upside risk payments from CMS to the IOTA participant of up to $15,000 per eligible kidney transplant or downside risk payments from the IOTA participant to CMS of up to $2,000 per eligible kidney transplant (refer to section IV.C. (Detailed Economic Analysis) of the 2024 Final Rule for a description of how upside and downside risk payments are calculated in the model). We project that payouts will far exceed the relatively small sum of downside risk payments expected over the 6-year model performance period. Only about $3 million in total downside risk payments are expected over the 6 years, with fewer than 26 percent of IOTA participants projected to owe downside risk payments in any of years 3 through 6. By contrast, we project that $76 million in total upside risk payments would be made over 6 years to roughly 26 percent of IOTA participants in the first year, rising to about 33 percent over the succeeding 5 model years.

Under the RFA, agencies are to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). Although many IOTA participants (that is, kidney transplant hospitals with NAICS 622110 General Medical and Surgical Hospitals) may be small entities as that term is used in the RFA, kidney transplants only represent a small fraction of the revenue such hospitals generate, and even the largest per transplant downside risk payment of $2,000 (which is not expected to apply to any hospitals at the median projection and only about 1 percent of hospitals at the 90th percentile projection) would not represent a significant economic impact. Additional sources of financial burden on IOTA participants to consider include the estimated cost of $6,346.00 per IOTA participant per year to review the organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries, $1,587 to notify patients about offers declined on their behalf, $1,587 to notify patients about changes in their waitlist status, and the one-time cost of $132.44 per IOTA participant to have their medical and health services manager review this rule. Refer to the sections titled, ''Estimated Burden on Participant Hospitals'' and ''Regulatory Review Cost Estimation'' in this proposed rule for an explanation of how these burden estimates were determined.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. The $6,346.00 cost per IOTA participant to review the organ offer acceptance criteria, the $1,587 for notifying patients about offers declined on their behalf, $1,587 for notifying patients about a change in status, and the $132.44 cost per IOTA participant to complete the regulatory review would represent 0.3 percent, 0.1 percent, 0.1 percent, and 0.007 percent, respectively, of the estimated total annual revenue per IOTA participant from inpatient claims with DRGs 008, 019, 650, 651, or 652 submitted for adult Medicare FFS or MA beneficiaries with Medicare as their primary or secondary payer. Based on these estimates, we do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, under section 1102(b) of the Act, a regulatory impact analysis should be prepared if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe this proposed rule would not have a significant impact on small rural hospitals. Currently, no small rural hospitals are IOTA participants and no additional IOTA participants are being proposed. Therefore, the Secretary has certified that this proposed rule will not

have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule will not have a substantial direct effect on state or local governments, preempt states, or otherwise have a Federalism implication.

J. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' For *E.O. 14192* accounting purposes, savings to the Federal government that are classified as transfers in regulatory impact analyses do not count as cost savings.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''**DATES**'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 5, 2025.

List of Subjects in 42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Recordkeeping requirements.

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 512 as set forth below:

■ 1. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 2. Section 512.402 is amended by:
■ a. Adding the definition for ''Eligible IOTA waitlist beneficiary'';
■ b. Removing the definitions for ''Health equity goals,'' ''Health equity plan intervention,'' ''Health equity plan performance measure(s),'' and ''Health equity project plan'';
■ c. Adding the definitions for ''Military medical treatment facility,'' ''MPSC'', and PRA;
■ d. Removing the definition for ''Resource gap analysis'';
■ e. Adding the definition for ''Single-organ kidney transplant'';
■ f. Removing the definition for ''Target health disparities'';
■ g. Adding the definition for ''Transplant organ offer acceptance criteria'';
■ h. Removing the definition for ''Underserved communities''; and
■ i. Adding definition for ''VA medical facility''.

The additions and revisions read as follows:

§ 512.402 Definitions.

* * * * *

Eligible IOTA waitlist beneficiary means an IOTA waitlist patient, as defined at § 512.402, who is a Medicare beneficiary and meets all of the following criteria:

(1) Is active on the IOTA participant's waitlist.

(2) Has accrued a minimum of 3 years of waiting time on the IOTA participant's waitlist.

* * * * *

Military medical treatment facility (MTF) means both of the following:

(1) Any fixed facility of the Department of Defense that is outside of a deployed environment and used primarily for health care.

(2) Any other location used for purposes of providing health care. services as designated by the Secretary of Defense as defined in *10 U.S.C. 1073c(j)(3).*

* * * * *

MPSC stands for Membership and Professional Standards Committee.

* * * * *

PRA stands for panel-reactive antibody.

* * * * *

Single-organ kidney transplant means the procedure in which a kidney alone is surgically transplanted from a living or deceased donor to a transplant recipient alone.

* * * * *

Transplant organ offer acceptance criteria means 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.

* * * * *

VA medical facility means 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 as defined in *38 CFR 17.1505.* A Vet Center, or Readjustment Counseling Service Center, is not a VA medical facility.

* * * * *

■ 3. Section 512.412 is amended by—
■ a. In paragraph (a) introductory text, removing the phrase ''meets both of the following'' and adding in its place the phrase ''meets all of the following''.
■ b. In paragraph (a)(1), removing the figure ''11'' and adding in its place the figure ''15''.
■ c. Adding paragraph (a)(3).

The addition reads as follows:

§ 512.412 Participant eligibility and selection.

(a) * * *

(3) The kidney transplant hospital is not a MTF or VA medical facility as defined at § 512.402.

* * * * *

■ 4. Section 512.428 is amended by—
■ a. Revising paragraphs (b)(1)(iii)(E) and (b)(1)(iv)(A);
■ b. Adding paragraph (b)(2) and reserving paragraph (b)(3);
■ c. Revising Table 1 to paragraph (d); and
■ d. Revising paragraphs (d)(1) and (2).

The revisions and additions read as follows:

§ 512.428 Quality Domain.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(E) Multi-organ transplants (except for kidney/pancreas transplants).

(iv)(A) When calculating the composite graft survival rate, CMS only includes single-organ kidney transplants, as defined at § 512.402, and kidney/pancreas transplants for

transplant recipients who are 18 years of age and older in the number of kidney transplants performed by the IOTA participant during each PY in the denominator.

* * * * *

(2) *Risk-adjustment.*

(i) *Risk-adjustment transplant recipient and donor characteristics.* In accordance with paragraphs (b)(1) through (3) of this section, CMS risk-adjusts the composite graft survival rate based on, at minimum, the following:

(A) Transplant recipient characteristics.

(1) Age.

(2) Sex.

(3) Kidney function (eGFR/creatinine).

(4) Diabetes status.

(5) Hypertension with or without cardiovascular disease.

(6) Human leukocyte antigen (HLA) mismatch.

(7) Plasma renin activity (PRA) levels.

(B) Donor characteristics.

(1) Age.

(2) Sex.

(3) Kidney function (eGFR/creatinine).

(4) Diabetes status.

(5) Hypertension history with or without cardiovascular disease.

(6) Cardiovascular disease.

(7) Human leukocyte antigen (HLA) mismatch.

(8) Plasma renin activity (PRA) levels.

(9) Cause of death.

(10) Donation after cardiac death.

(ii) *Risk-adjustment methodology.*

(A) *Risk analysis.* CMS analyzes the transplant recipient and donor characteristics as specified in paragraphs (b)(2)(i)(A) through (D) of this section.

(B) *Risk scoring.* CMS applies a risk score to each individual IOTA kidney transplant patient, as defined at § 512.402, based on the analysis of the transplant recipient and donor characteristics in paragraph (ii)(A) of this section.

(C) *Adjustment and comparison.* CMS uses the calculated composite graft survival rate risk scores identified in paragraph (2)(ii)(B) of this section to—

(*1*) Normalize the composite graft survival rate outcome to control for differences in transplant recipient risk.

(*2*) Adjust the composite graft survival rate, based on the normalized composite graft survival rate outcome.

* * * * *

(3) Reserved.

(d) * * *

TABLE 1 TO PARAGRAPH (d)—IOTA MODEL COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance relative to national ranking	Lower bound condition	Upper bound condition	Points earned
80th Percentile	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

■ 5. Section 512.430 is amended by—

■ a. In paragraph (b)(1) introductory text, removing the phrase ''is 60 points or above,'' and adding in its place the phrase ''is above 60 points,'';

■ b. In paragraph (b)(2)(ii), removing the phrase ''between 41 to 59 points (inclusive),'' and adding in its place the phrase ''between 40 to 60 points (inclusive)'';

■ c. In paragraph (b)(3) introductory text, removing the phrase ''is at or below 40 points'' and adding in its place the phrase ''is below 40 points''; and

■ d. Revising paragraph (d)(6)(ii).

The revision and addition read as follows:

§ 512.430 Upside risk payment, downside risk payment, and neutral zone.

* * * * *

(d) * * *

(6) * * *

(i) * * *

(ii) The IOTA participant must pay 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, CMS will invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, in accordance with 31 U.S.C. 3711(g).

■ 6. Section 512.436 is amended by revising paragraphs (a)(1) and (b) introductory text to read as follows:

§ 512.436 Extreme and uncontrollable circumstances.

(a) * * *

(1) May at its sole discretion provide flexibilities to an IOTA participant if the IOTA participant is located in—

(i) An emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and

(ii) A county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas.

(b) *Impact on payments.* In the event of an extreme and uncontrollable circumstance, as described in paragraph (a) of this section, CMS may adjust the magnitude and direction of the IOTA participant's upside or downside risk payment, if applicable, prior to recoupment or payment, if the IOTA participant is participating in the IOTA Model when CMS has declared such an emergency period. CMS may determine any adjustment made based in part on the following:

* * * * *

■ 7. Section 512.442 is amended by—

■ a. Revising paragraphs (a) and (b);

■ b. In paragraph (c) introductory text, removing the phrase ''acceptance criteria with'' and adding in its place the phrase ''acceptance criteria (as defined at § 512.402) with'';

■ c. Revising paragraphs (c)(1) and (2);

■ d. Adding paragraph (d).

The revisions and addition read as follows:

§ 512.442 Transparency requirements.

(a) *Publication of selection criteria.* (1) The IOTA participant must publicly post on its website the criteria used by the IOTA participant for evaluating and selecting patients for addition to their kidney transplant waitlist by the end of PY 1.

(2) For all subsequent PYs, 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 is up on its website to date by the end of each relevant PY.

(3) IOTA participants performing living donor kidney transplants must—

(i) Publicly post on its website its living donor selection criteria for evaluating potential living donors for

kidney transplant waitlist patients by the end of PY 2; and

(ii) For all subsequent PYs, review its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients and ensure that the information on its website is correct by the end of each relevant PY.

(b) *Transparency into kidney transplant organ offers.* For PYs 3 through 6, the IOTA participant must do the following for all eligible IOTA waitlist beneficiaries, as defined at § 512.402:

(1) Inform eligible IOTA waitlist beneficiaries of the number of times an organ is declined on the eligible IOTA waitlist beneficiary's behalf, unless the eligible IOTA waitlist beneficiary opts out of receiving this notification.

(i) For each 6-month period in which an organ offer is received and declined, provide notifications to each eligible IOTA waitlist beneficiary that include all of the following:

(A) How much wait-time the eligible IOTA waitlist beneficiary is currently listed with and their percent PRA value.

(B) 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.

(C) 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 patient.

(D) The refusal reason(s) why offers were declined based off OPTN refusal codes in plain language.

(E) Of the deceased donor kidney organ offers declined for that eligible IOTA waitlist beneficiary, how many of those declined offers were transplanted into another kidney transplant patient.

(F) Potential avenues to accelerate access to transplant.

(ii) [Reserved]

(2) The IOTA participant must provide the notification described in paragraph (b)(1) of this section via patient visit, email, electronically, or mail on an individual basis, unless the eligible IOTA waitlist beneficiary opts out of receiving this notification.

(i) IOTA participants must give eligible IOTA waitlist beneficiaries the opportunity to opt out of receiving the notification described in paragraph (b)(1) of this section.

(ii) If an eligible IOTA waitlist beneficiary opts out of receiving this notification, the IOTA participant must do both of the following:

(A) Record in the eligible IOTA waitlist beneficiary's medical record all of the following:

(*1*) The date on which this notification was declined.

(*2*) The method by which this notification was declined.

(B) Offer to provide this notification once every 6 months at which time the eligible IOTA waitlist beneficiary will have the opportunity to opt out of receiving this notification again.

(3) Record all of the following in the eligible IOTA waitlist beneficiary's medical record:

(i) That the eligible IOTA waitlist beneficiary received the information specified in paragraph (b)(1) of this section.

(ii) The method by which this notification was delivered.

(iii) The date by which this notification was delivered.

(4) Provide the information specified in paragraph (b)(1) of this section to the eligible IOTA waitlist beneficiary's nephrologist or nephrology professional.

(c) * * *

(1) * * *

(i) Prior to reviewing transplant organ offer acceptance criteria, as defined at § 512.402, with IOTA waitlist patients who are Medicare beneficiaries, IOTA participants must give these beneficiaries an opportunity to decline this review.

(ii) If an IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant must do both of the following:

(A) Record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

(*1*) The date on which this review was declined.

(*2*) The method by which this review was declined.

(B) Offer the IOTA waitlist patient who is a Medicare beneficiary the opportunity to review transplant organ offer acceptance criteria once every 6 months at which time the IOTA waitlist patient who is a Medicare beneficiary will have the opportunity to decline this review again.

(2) The IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

(i) The information specified in paragraph (c) of this section was reviewed with the IOTA waitlist patient who is a Medicare beneficiary.

(ii) The date in which this review took place.

(iii) The method by which this review was delivered.

(d) *Change in waitlist status notification.* (1) The IOTA participant must do the following for all IOTA waitlist patients who are Medicare beneficiaries during the model performance period:

(i) Inform IOTA waitlist patients who are Medicare beneficiaries any time their status on the waitlist is changed that would impact their ability to receive an organ offer.

(ii) When there is a change in waitlist status, provide notifications to each IOTA waitlist patient who is a Medicare beneficiary that includes all of the following:

(A) The most recent date the IOTA waitlist patient who is a Medicare beneficiary became inactive.

(B) The reason for the change in waitlist status.

(C) That the IOTA waitlist patient who is a Medicare beneficiary cannot receive organ offers while inactive.

(D) Information on how the IOTA waitlist patient who is a Medicare beneficiary may become active on its waitlist again.

(E) How the IOTA waitlist patient who is a Medicare beneficiary may contact the IOTA participant for more information or with any questions.

(iii) The IOTA participant must provide this notification (as described in paragraph (d)(1)(i) of this section), and the information specified in paragraph (d)(1)(ii) of this section as follows:

(A) Electronically or by mail on an individual basis.

(B) Within 10 days of the IOTA waitlist patient who is a Medicare beneficiary's change in waitlist status.

(C) Annually, thereafter, for as long as the IOTA waitlist patient who is a Medicare beneficiary remains inactive (that is, 365 consecutive days).

(2) Record in the IOTA waitlist patient who is a Medicare beneficiary's medical record a copy of the notification that includes all of the following:

(i) The method by which the notification was delivered.

(ii) The date of when the notification was delivered.

(3) For IOTA waitlist patients who are Medicare beneficiaries and—

(i) ESRD patients, the IOTA participant must also notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at *§ 512.310*) or nephrologist.

(ii) Non-ESRD patients, the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient who is a Medicare beneficiary.

§ 512.446 [Removed]

■ 8. Subpart D is amended by removing § 512.446.

■ 9. Section 512.450 is amended by—

■ a. In paragraph (a)(1), removing the phrase ''attributed patients that'' and adding in its place the phrase ''attributed patients who are Medicare beneficiaries that''; and
■ b. Revising paragraph (a)(3)(iii).
The revision reads as follows:

§ 512.450 Required beneficiary notifications.

(a) * * *
(2) * * *
(3) * * *
(iii)(A) Provide the notification described in paragraph (a) of this section to each applicable attributed patient in a paper format at their first office visit or other outpatient visit after the start of the Model; or
(B) If the attributed patient has affirmatively opted out of receiving paper communication and has chosen to receive communication through electronic methods, the notification described in paragraph (a) of this section may be distributed through that agreed upon electronic method.
* * * * *

■ 10. Section 512.462 is amended by adding paragraph (b)(2)(xi) to read as follows:

§ 512.462 Compliance and monitoring.

* * * * *
(b) * * *
(2) * * *
(xi) Monitoring the publication of selection criteria provision in accordance with § 512.442(a).
(xii) Monitoring the transparency into kidney transplant organ offers provision in accordance with § 512.442(b).
(xiii) Monitoring the review of acceptance criteria provision in accordance with § 512.442(c).
(xiv) Monitoring the change in waitlist status provision in accordance with § 512.442(d).
* * * * *

■ 11. Section 512.466 is amended by revising and republishing paragraph (a)(3)(ix) to read as follows:

§ 512.466 Termination.

(a) * * *
(3) * * *
(ix) Poses significant program integrity risks, including but not limited to any of the following:
(A) Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency.
(B) Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:
(*1*) Being subject to the filing of a complaint or, filing of a criminal charge.
(*2*) Being subject to an indictment.
(*3*) Being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.
(C) If HHS or the OPTN has determined that an IOTA participant has violated the OPTN's policies, OPTN's Management and Membership policies, or HHS's regulation (*42 CFR 121*) upon a review conducted pursuant to *42 CFR 121.10.*
* * * * *

Robert F. Kennedy, Jr,

Secretary, Department of Health and Human Services.

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