DEPARTM

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS-5544-F]

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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: Final rule.

SUMMARY: This final rule will update and revise the Increasing Organ Transplant Access (IOTA) Model for Performance Year (PY) 2. This final rule also includes a technical correction to the regulatory text.

DATES: These regulations are effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background and Executive Summary

A. 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 final rule will update IOTA Model provisions in response to improvement opportunities that arose during implementation of the 2024 Final Rule 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.

B. Executive Summary

1. Purpose

In the December 11, 2025 **Federal Register** (90 FR 57598), we published the proposed rule titled "Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA)" (hereafter referred to as the 2025 Proposed Rule). In response to the 2025 Proposed Rule, we received 114 timely pieces of correspondence from a variety of commenters, including providers, health plans, health care companies, professional associations, technology companies, dialysis facilities, and individuals.

This final rule will 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.

We are finalizing some, but not all, of the provisions discussed in the proposed rule (hereinafter referred to as the 2025 Proposed Rule), and we intend to address certain other provisions discussed in the 2025 Proposed Rule in future rulemaking. This final rule also makes a technical correction to the regulation text for methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant by redesignating § 512.414(b)(3)(A) through (D) as § 512.414(b)(3)(i) through (iv). We also note that some of the public comments were outside of the scope of the 2025 Proposed Rule. These out-of-scope public comments are

not addressed in this final rule. We have summarized the public comments that are within the scope of the 2025 Proposed Rule and have included our responses to those public comments. However, we note that in this final rule we are not addressing most comments received with respect to the provisions of the 2025 Proposed Rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate. We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from other parts of this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this final rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this final rule. A general summary of the changes in this final rule is presented in section II.B of the preamble of this final 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 sections 1835(d) and 1862(a)(3) of 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 federal government entity, with only limited exceptions. Therefore, we are finalizing our proposed modification to 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 final 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 final rule, we are finalizing our proposal 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 will be finalized after the model start date. In the 2025 Proposed Rule, CMS proposed to include a risk-

adjustment methodology in the composite graft survival rate calculation. Specifically, we proposed that CMS would risk-adjust the composite graft survival rate to account for a minimum set of transplant recipient and donor characteristics. As described in section II.B.2.b.(2).(a). of this final rule, we are finalizing updates to the composite graft survival rate metric that will include the following modifications:

- Adding a modified risk-adjustment framework based on the Scientific Registry of Transplant Recipients' (SRTR's) risk adjustment methodology for the 1-year graft survival metric.

- 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 finalized policy change and the corresponding scoring criteria can be found in section II.B.2.b. of this final 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.

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[1]. In the 2025 Proposed Rule, we considered including beneficiaries with Medicare Advantage (MA) as well in the definition of Medicare kidney transplants in order to include MA beneficiaries in the calculations for the upside risk payment and downside risk payment. Based on the comments received, and as described in section II.B.3.b. of this final rule, we are finalizing the inclusion of MA beneficiaries in the calculation of the upside risk payment and downside risk payment. We had considered lowering the maximum upside payment for a kidney transplant performed from $15,000 to $10,000 alongside this provision but are not finalizing this provision due to comments from stakeholders.

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 final rule, CMS is finalizing a modification to 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 finalized in section II.B.3.c.(2). of this final 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

1 See Table 12 in the 2024 Final Rule (89 FR 96381) for a full description of MS-DRGs 008, 019, 650, 651 and 652.

PY. The current regulations provide that, in the event of an extreme and uncontrollable circumstance, as determined by the QPP, CMS may reduce the downside risk payment, if applicable, prior to recoupment. CMS determines the amount of the reduction by multiplying the downside risk payment by both the percentage of total months during the PY affected by the EUC and the percentage of attributed patients who reside in an area affected by the EUC. CMS 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 if allocation systems were disrupted due to an emergency or if there were disaster conditions that could disproportionately affect post-transplant outcomes, 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.

In the 2025 Proposed Rule (90 FR 57612) CMS proposed to update the EUC policy so that at its sole discretion, CMS may 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 proposed 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 proposed 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. Due to commenter feedback, we are finalizing this proposal with modification. We are not finalizing our proposal to apply EUC flexibilities during an emergency period as defined in section 1135(g) of the Act, but to instead continue to use EUC as defined by the Quality Payment Program. We are finalizing our proposals to extend payment and reporting flexibilities to IOTA participants impacted by EUC

and to 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 from IOTA participants, which CMS would have liked to incorporate into the IOTA Model, but was unable to add to the 2024 Final Rule. Therefore, the 2025 Proposed rule proposed updates to other requirements in the IOTA Model.

(1) Transparency

In the 2024 Final Rule CMS finalized our policy 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. In the 2025 Proposed Rule (90 FR 57613), CMS proposed updates to these requirements. As such, this final rule updates requirement that include 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 this information is up to date by the end of each subsequent PY.

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

CMS also finalized its policy 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 discussed in section II.B.4.a.(2). of this final rule, we finalized a requirement to publish IOTA participant waitlist selection criteria and the living donor selection criteria, as described in section II.B.4.a.(1). of this final rule, on the IOTA Model website by the end of the second quarter of each subsequent PY.

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. Since the publication of the 2024 Final Rule, IOTA participants have 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 final 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 defining "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, in the 2025 Proposed Rule (90 FR 57618 through 57621), CMS proposed 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: 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 will 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). CMS is finalizing this provision without modification, as discussed in detail in section II.B.4.a.(5). of this final rule.

(2) 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, CMS is removing the voluntary HEP provisions in compliance with Executive Order 14151 Ending Radical and Wasteful Government DEI Programs and Preferencing (90 FR 8339) issued January 20, 2025 and because, although voluntary, they still require participant time and resources and CMS believes those resources are better directed to the model's core objectives and mandatory requirements.

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. In the 2025 Proposed Rule (90 FR 57621 through 57622), CMS proposed the following updates:

- 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 and has chosen to receive communication through electronic methods.

As described in section II.B.5. of this final rule, we have finalized these proposals with

the modification that IOTA participants may distribute the notification in an electronic format in cases where the attributed patient has affirmatively opted out of receiving paper communications or has chosen to receive communication through electronic methods.

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 final rule we are finalizing with modification that CMS may monitor the following transparency provisions as described in section II.B.6 of this final rule:

- Informing eligible IOTA waitlist patients who are Medicare beneficiaries, as defined in section II.B.4.a.(3). of this final rule, of the number of times an organ is declined on the Medicare beneficiary's behalf in accordance with finalized § 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 finalized § 512.442(d).

g. 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 final rule, the 2024 Final Rule 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 final rule we are

finalizing our policy, with minor technical corrections as described in section II.B.7 of this final rule, 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 HHS regulations (42 CFR part 121) upon a review conducted in accordance with 42 CFR 121.10.

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 final rule, we set forth a detailed analysis of the impacts that the proposed changes will have on the IOTA participants and beneficiaries. We estimate that as a result of the finalized changes to the IOTA Model, net Federal savings will increase by $60 million.

II. 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 selected 103 kidney transplant hospitals to participate in the IOTA Model for the first performance year 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 from IOTA participants, which CMS would like to incorporate into the IOTA Model, but were unable to add to the 2024 Final Rule. Therefore, the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (hereinafter referred to as the 2025 Proposed Rule), published December 11, 2025, proposed updates to the IOTA Model. The policies finalized in this final 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 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 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 for PY 1 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 in 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 stated we believed 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 (90 FR 57603). We also received multiple comments from the 2024 Proposed Rule urging us to increase the low volume threshold. As such, in the 2025 Proposed Rule, we proposed 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 also proposed this provision in response to our experience in operating the model. IOTA participants who are above the current minimum low volume threshold of 11 kidney transplants performed annually, but below the updated proposed low volume 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 (90 FR 57603). We stated in the 2025 Proposed Rule that the updated low volume threshold would only result in the removal of one IOTA participant as of the model start date, while higher low volume thresholds would result in additional IOTA participants being removed, which could diminish the ability to evaluate the model.

We sought 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 sought public comment on the alternatives considered.

Additionally, we stated in the 2025 Proposed Rule that since the publication of the 2024 Final Rule, CMS completed IOTA participant selection and notified IOTA participants of their selection to participate in the IOTA Model (90 FR 57603). 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.

As discussed in the 2025 Proposed Rule, per 42 CFR 411.6(a), Medicare does not pay for

services rendered by Federal providers of services or other Federal agencies (90 FR 57603). 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 proposed to update the participant eligibility criteria at § 512.412(a). Specifically, we proposed 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 proposed 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 (90 FR 57603). Additionally, we proposed 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 stated that we believed that VA medical facilities and MTFs should not be eligible to participate in the IOTA Model (90 FR 57603). Additionally, we stated that we did 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, impact the IOTA Model, or affect CMS's ability to evaluate the model. Moreover, we stated that 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, we stated that including non-Medicare participating facilities like VA medical facilities and MTFs

would introduce confounding variables that could obscure the model's true effectiveness. Additionally, we stated that 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, we stated that the model evaluation can focus on kidney transplant 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 (90 FR 57604). We stated that 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 sought 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 sought 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 proposed updating the language at § 512.412(a) (90 FR 57604). Specifically, we proposed 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 sought 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).

The following is a summary of the comments we received on the provisions proposed and the alternatives considered set out in this section and our responses.

Comment: Several commenters expressed support for the proposal to raise the low volume threshold to a minimum of 15 kidney transplants performed annually during each of the baseline years for patients aged 18 years or older, regardless of payer, instead of the current low volume threshold of 11. Additionally, several commenters agreed with CMS that the proposed update would balance the need to have statistical validity with consideration for the IOTA participants. Another commenter stated that the proposed change would strengthen model integrity and that it is supported across professional societies.

Response: We thank the commenters for their support. We agree that raising 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 will strengthen model integrity. We stated in the 2025 Proposed Rule that the proposed change would better take into consideration the needs of smaller kidney transplant hospitals and would ensure that their transplant programs can remain viable and continue to serve their communities (90 FR 57603). For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters expressed support for the proposal at § 512.412(a)(1) to raise the low-volume threshold to a minimum of 15 kidney transplants performed annually during each of the baseline years for patients aged 18 years or older, regardless of payer, instead of the current threshold of 11. However, commenters requested additional information regarding the proposed change. In particular, a commenter recommended that CMS provide a clearer explanation of the rationale for increasing the threshold and disclose the number and characteristics of kidney transplant hospitals that would be affected. The commenter also suggested that CMS monitor the impact of implementing the revised threshold.

Response: We thank the commenters for their support, feedback, and suggestions. We

stated in the 2025 Proposed Rule that our rationale for raising the low volume threshold was a result of IOTA participant feedback concerning the structural difficulties in meeting model goals, commenters responding to the 2024 Proposed Rule urging CMS to increase the low volume threshold, and our experience in operating the model (90 FR 57603). Additionally, we note that we intend to publicly post an updated list of IOTA participants on the IOTA Model website.

Comment: A couple of commenters asked CMS to provide additional information or analysis proving that the proposal to adjust the low volume threshold from 11 to 15 kidney transplants would improve statistical validity or model performance. Another commenter asked CMS to provide additional data concerning how the change would impact health care access in less populous regions.

Response: We thank the commenters for their comments. As described in the 2024 Final Rule, the model's design ensures sufficient participation of kidney transplant hospitals, which is necessary to obtain a diverse, representative sample for a statistically robust test of the model (89 FR 96307). We do so in accordance with section 1115A(b)(4) of the Act. As stated in the 2024 Proposed Rule, we continue to believe the proposed, updated 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, as described in the 2025 Proposed Rule and this final rule, the proposed updated low volume threshold would only result in the removal of one IOTA participant as of the model start date (90 FR 57603). We intend to monitor the model for any unintended consequences.

Comment: A couple of commenters expressed concern that increasing the low-volume threshold to 15 kidney transplants performed annually during each of the baseline years for patients aged 18 years or older, regardless of payer, could discourage innovation or create access barriers for low-volume kidney transplant hospitals, particularly those serving rural and underserved populations. These commenters recommended alternative approaches, including adopting a tiered eligibility framework based on transplant volume, as well as incorporating risk-

adjustment, performance benchmarks, phased participation, or enhanced technical assistance to support broader participation and benefit for lower-volume transplant hospitals.

Response: We thank the commenters who expressed concerns around the impact of raising the low volume threshold to 15 kidney transplants. However, we disagree with the commenters. We recognize that our proposal to raise the low volume threshold to 15 kidney transplants performed annually during each of the baseline years would exclude smaller kidney transplant hospitals. However, as stated previously in the 2025 Proposed Rule and discussed in the preamble of this final rule, our proposal to raise the low volume threshold would only result in the removal of one IOTA participant as of the model start date (90 FR 57603). However, as stated in comment responses noted previously in this section, we are finalizing 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. We note that the model includes features such as risk-adjustment and performance measurement approaches designed to account for differences in patient complexity and care environments. In addition, we intend to monitor the effects of the low volume threshold on participation and access to care, including impacts on low volume kidney transplant hospitals and the populations they serve. While we are not adopting the alternative approaches suggested by commenters at this time, we will continue to evaluate the need for potential refinements, including additional supports or adjustments, through future notice and comment rulemaking as appropriate.

Comment: A couple of commenters recommended that CMS further increase the low volume threshold, suggesting levels such as 30, 50, or 100 kidney transplants, to avoid burdening kidney transplant hospitals that furnish a smaller number of kidney transplants. A commenter stated that a higher low volume threshold would help ensure that participating kidney transplant hospitals are able to offset the infrastructure costs associated with model participation. Another

commenter recommended pairing a higher low volume threshold with an exclusion for kidney transplant hospitals serving rural and underserved populations.

Response: We thank the commenters who suggested using an even higher low volume threshold beyond 15 adult kidney transplants; however, we disagree with the commenters. As described in the 2025 Proposed Rule, adopting a higher threshold would result in additional IOTA participants being removed from the model, which could diminish CMS's ability to evaluate the model (90 FR 57603). IOTA participants may have to make upfront investments to accommodate the model's requirements, but we believe that the proposed low volume threshold of 15 adult kidney transplants performed for each kidney transplant hospital in each of the baseline years will mitigate demands placed on smaller kidney transplant hospitals. In response to the commenter who suggested that CMS raise the low volume threshold higher and exclude kidney transplant hospitals serving rural and underserved populations, as described in the 2024 Proposed Rule, we stated that we did not believe mandatory participation in the IOTA Model would increase disparities for underserved populations such as dual-eligibles or low-income subsidy beneficiaries, nor for rural transplant hospitals (89 FR 96306). Additionally, as stated in the 2024 Proposed Rule, we continue to believe that IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants (89 FR 43542).

Comment: Several commenters expressed support for the proposed exclusion of kidney transplant hospitals that are a MTF or VA medical facility given that the change would ensure that removing these kidney transplant hospitals would make it easier to compare performance for the purposes of evaluation. Several commenters noted that the model's payment and quality incentives may have different effects on VA medical facilities and MTFs.

Response: We thank the commenters for their support and thoughts regarding the advantages of the proposed change. We agree with the commenters. Accordingly, we are finalizing the proposal at § 512.412(a)(3) to exclude kidney transplant hospitals that are a MTF

or VA medical facility as eligible to participate in the model.

Comment: A commenter stated that they did not support the proposed exclusion of these facilities, but did not provide further suggestions or justification.

Response: We thank the commenter for their feedback.

Comment: A commenter supported CMS's proposed definitions for MTF and VA medical facility, but did not provide a rationale for their support.

Response: We thank the commenter for their support of the proposed definitions.

Comment: Several commenters stated that they supported the proposed modification replacing "meets both" with "meets all", but did not provide further suggestions or justification.

Response: We thank the commenters for their support of the proposed update to existing language to account for our proposed kidney transplant hospital participant eligibility criteria. We are finalizing the proposal at § 512.412(a) to update existing language to account for our proposed kidney transplant hospital participant eligibility criteria at proposed § 512.412(a)(1) and (3).

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions for participant eligibility criteria for kidney transplant hospitals at § 512.412(a) without modification. Additionally, we are finalizing as proposed the definitions of Military medical treatment facility (MTF) and VA medical facility without modification.

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

[2] We note that we did not include a definition or criteria for what constitutes "acceptable" post-transplant outcomes and we sought 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 final rule.

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 increase 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, 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.

As stated in the 2025 Proposed Rule at 90 FR 57605 , 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 the 2025 Proposed Rule, we proposed at § 512.428(b)(2) to include a risk-adjustment methodology in the composite graft survival rate calculation. Specifically, we proposed 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.

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*

++ Sex.

++ Kidney function (eGFR/creatinine).

++ Diabetes status.

++ Hypertension with or without cardiovascular disease.

++ Human leukocyte antigen (HLA) mismatch.

++ Plasma renin activity (PRA) levels[4].

- 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[5].

++ Cause of death.

++ Donation after cardiac death.

In the 2025 Proposed Rule, we stated our belief that the proposed transplant recipient and donor characteristics represent well-established, non-modifiable predictors that significantly influence graft survival independent of care quality (90 FR 57605). 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

[4] Subsequent to the publication of the 2025 Proposed Rule, we have found that the wrong term was inadvertently used; we clarify that actually the term that should have been used was Panel Reactive Antibody (PRA) levels.
[5] Subsequent to the publication of the 2025 Proposed Rule, we have found that the wrong term was inadvertently used; we clarify that actually the term that should have been used was Panel Reactive Antibody (PRA) levels.

fair assessment.[6,7] Diabetes, hypertension, and cardiovascular disease represent major outcome determinants present at transplantation that are largely beyond transplant hospitals' short-term control.[8,9,10] 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.[11] 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.[12,13] 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.[14]

In the 2025 Proposed Rule, we proposed at § 512.428(b)(2)(ii)(A) that CMS would analyze the transplant recipient and donor characteristics as specified at proposed §

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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 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*

9 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

10 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

11 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.0b013e31823f14d4*

12 Ibid

13 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*

14 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*

512.428(b)(2)(i)(A) and (B) (90 FR 57605). We also proposed 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 proposed 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.

In the 2025 Proposed Rule, we stated our belief that 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 (90 FR 57606). 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.[15] 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 risk-adjustment modeling, we believed 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 sought comments on our proposed composite graft survival rate risk-adjustment methodology at proposed § 512.428(b)(2). We also sought comment on what transplant recipient and donor characteristics, infectious disease status or other medically complex factors,

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15 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*

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.

As stated in the 2025 Proposed Rule (90 FR 57606), 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 OPTN and CMS in existing programs (90 FR 57606). 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[16]. 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

16 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*

with deceased and living donors, which includes a defined list of transplant recipient and donor characteristics included in the calculation that are updated periodically.[17] 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.[18,19] However, we believed 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.[20]

Additionally, SRTR implements more frequent model rebuilds in addition to refitting the models every 6 months (90 FR 57606). 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

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17 Technical methods for the Program-Specific reports. (n.d.-b). *https://www.srtr.org/transplant-professionals/program-specific-report/technical-methods-for-the-program-specific-reports/*

18 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*

19 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*

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

encouraging risk aversion (90 FR 57607).[21,22,23,24,25,26] 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.[27] There have been persistent questions about "whether the OPTN data are adequate for risk-adjustments used in SRTR program-specific reporting."[28] 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 enhance the accuracy and fairness of IOTA Model evaluations.[29] 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

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21 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.0000000000000030* 1

22 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*

23 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*

24 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*

25 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*

26 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*

27 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

28 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*

29 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*

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[30], 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 (90 FR 57607). In this methodology, censored observations[31] 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.[32] Cox regression models have been cited for strong performance with extreme categories, discriminative power, and interpretable results.[33,34,35] 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

30 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.

31 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.

32 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*

33 Ibid.

34 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

35 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*

framework.[36,37] While we recognized 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 (90 FR 57607). This method applies standard population risk profiles[38] to all IOTA participants. Advantages to this method include simple interpretation and precedence in Care Compare.[39] 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 (90 FR 57607). 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).[40, 41] We chose not to propose this approach because of the

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36 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*

37 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*

38 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.

39 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*

40 Ibid.

41 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*

complexity of designing a robust risk model.

We considered, but did not propose, a hierarchical logistic regression approach with indirect standardization (90 FR 57607). This approach models graft survival probability at the individual transplant recipient level and accounts for kidney transplant hospital-level clustering effects.[42, 43] 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

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

$Where$:

- $P_{ij} = probability\ of\ graft\ survival\ for\ kidney\ transplant\ patient\ i\ in\ IOTA\ participant\ j$
- $u_j \sim N(0, \sigma_u^2) represents\ random\ IOTA\ participant - level\ effects$
- $\beta^0 = intercept$
- $\beta^1 - \beta^6 = fixed\ effect\ coefficients\ for\ risk\ adjustment\ variables$

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 acknowledged that this approach demonstrates substantial technical merit, we believed that the level of complexity inherent in a hierarchical logistic regression statistical

42 Hoffman, J. I. (2015). Survival analysis. In *Elsevier eBooks* (pp. 621–643). *https://doi.org/10.1016/b978-0-12-802387-7.00035-4*
43 Hoffman, J. I. (2015a). Logistic regression. In *Elsevier eBooks* (pp. 601–611). *https://doi.org/10.1016/b978-0-12-802387-7.00033-0*

model structure would introduce operational risks and administrative burden. Transplant hospital-level variation may not be significant enough to warrant the added complexity,[44] 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 (90 FR 57607). 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.[45]

We sought comment on the alternatives considered. Although we did not propose to include a risk-adjustment methodology that also accounts for time-to-event data, we sought 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 sought 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). As stated in the 2025 Proposed Rule, 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 (90 FR 57608). 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

44 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*
45 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*

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 the 2025 Proposed Rule, we proposed to update the regulation at § 512.428(b)(1)(iii)(E) to exclude multi-organ transplants (except for kidney/pancreas transplants) from the numerator (90 FR 57598). As a result, we also proposed 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 proposed 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 sought comment on our proposed definition of single-organ kidney transplant at proposed § 512.402.

As stated in the 2025 Proposed Rule, we proposed 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 (90 FR 57608).[46] 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 proposed 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.[47] Kidney/pancreas transplantation offers a potential cure for both diabetes and kidney failure in this population.[48] 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.[49] We further note 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 sought comment on our proposals at proposed § 512.428(b)(1)(iii)(E) and (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.

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46 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*

47 Ibid.

48 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

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

We considered retaining the inclusion of multi-organ transplantation in the calculation of the composite graft survival rate and solely revising the text of the regulation for clarification purposes (90 FR 57609). From 2000 to 2020 deceased donor kidney transplant volume doubled, while multi-organ transplants involving kidneys increased 6-fold during the same period. 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. 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.

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 (90 FR 57609). However, we chose not to propose 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.

We sought comment on the alternatives considered. We also sought comment on whether CMS should include multi-organ transplants in the numerator and denominator and which multi-organ transplants should CMS include or exclude.

The following is a summary of the public comments received on all of the calculation of metric proposals and alternatives considered set out in this section and our responses:

Comment: Many commenters expressed support for including risk-adjustment in the composite graft survival measure. Commenters stated that risk-adjustment promotes fairness and accuracy in performance measurement, prevents IOTA participants serving medically complex

patient populations from being penalized, and aligns incentives with the goal of expanding transplant access. Commenters also noted that risk-adjustment facilitates meaningful comparisons across IOTA participants and may reduce risk averse behavior. Several commenters emphasized that risk-adjustment is critical to achieving the goals of the IOTA Model.

Some of these commenters noted that without risk-adjustment, IOTA participants may face unintended pressure to avoid higher risk donors or recipients in order to protect performance scores, which could be counterproductive to the model's objectives of increasing kidney transplant volume and reducing waitlist mortality.

Response: We appreciate the feedback from commenters, and we agree about the importance of including a risk-adjustment methodology in the calculation of the composite graft survival rate metric in the quality domain. As stated in the 2025 Proposed Rule (90 FR 57606), we believe that including a risk-adjustment methodology for the composite graft survival rate to account for inherent donor and transplant recipient conditions that significantly influence graft survival, independent of care quality, supports meaningful and equitable performance measurement.

Comment: Many commenters urged CMS to adopt the existing SRTR risk-adjustment methodology rather than developing a separate approach for the IOTA Model, citing concerns that the proposed risk-adjustment methodology lacked sufficient clinical input and validation, may be complex to implement, could incentivize risk-averse behavior, and may not meaningfully affect a cumulative measure over time while potentially failing to keep pace with evolving clinical practice.

In the context of alternative considerations, several commenters stated that SRTR has the expertise and access to national data necessary to support development of a composite graft survival model that incorporates clinically validated variables and can be updated regularly to reflect evolving practices and emerging factors. In addition, a commenter noted that using SRTR

data could reduce administrative burden because transplant programs and organ procurement organizations already submit these data through existing reporting systems. The commenter further cited prior analysis estimating the cost of additional data collection and emphasized the importance of considering such burden when evaluating alternative approaches.

Commenters also stated that the SRTR risk-adjustment methodology is validated, evidence-based, and widely used in the transplant community. Commenters noted that it aligns with existing standards, includes established processes for data review and correction, reduces duplicative reporting burden, and is updated on a regular basis with input from clinical experts.

Response: Given the numerous concerns from stakeholders regarding the proposed risk-adjustment methodology for calculating the composite graft survival rate, we recognized an updated risk-adjustment methodology may be necessary to strengthen the model. As indicated in the 2025 Proposed Rule (90 FR 57606) and discussed in the preamble of this final rule, we considered using SRTR's adult kidney graft survival first-year post-transplant models for both deceased donor and living donor kidney transplants,[50] as well as a simplified approach utilizing a more limited set of characteristics than those employed by SRTR. Ultimately, for the reasons set forth in the 2025 Proposed Rule, we decided against either approach because, despite its sophistication and empirical support, it introduces substantial operational complexity and stronger incentives for risk aversion that could undermine the IOTA Model's goal of increasing kidney transplant volume. Additionally, we believed that these approaches could require extensive interpretive effort and additional resources from transplant hospitals, OPOs, and national partners. Instead, in the 2025 Proposed Rule, we constructed, and proposed, a risk-adjustment methodology to ensure that the composite graft survival rate accurately reflects true differences in quality of care by controlling for well established, nonmodifiable kidney transplant recipient and donor risk factors that meaningfully influence graft survival, thereby promoting

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

equitable comparisons across IOTA participants and reducing incentives to avoid higher risk patients. We direct readers to section II.B.2.b(2)(a) of this final rule for a full discussion on the risk-adjustment methodology proposed in the 2025 Proposed Rule. However, we recognize that there may be a more appropriate balance between the more complex methodologies we considered and the simpler methodology we proposed, which aims to reduce complexity while supporting a more attainable and practical approach for IOTA participants.

We conducted additional analysis that examined one of the risk-adjustment methodologies that we considered for calculating composite graft survival rate as described in section II.B.2.b(2)(a) of the 2025 Proposed Rule. Specifically, based on public comment, we reexamined whether we could incorporate SRTR's risk-adjustment methodology into the composite graft survival rate. We compared this methodology to what we proposed, as described in this section of this final rule, to determine whether an alternative risk-adjustment methodology for calculating the composite graft survival rate would be potentially more attainable.

Based on additional analysis and the commenters' concerns about the proposed risk-adjustment methodology, we are finalizing an updated risk-adjustment methodology in the calculation of the composite graft survival rate as follows:

Beginning in PY 2, for each PY, CMS will risk-adjust the observed graft survival rate to account for differences across IOTA participants in donor and candidate characteristics expected to influence graft survival. First, CMS will calculate the observed composite graft survival rate using the following equation (see Equation 2), where the observed composite graft survival rate is the IOTA participant's actual composite graft survival rate, as finalized in Equation 1 to Paragraph (b)(1) at § 512.428, with a Bayesian adjustment applied for statistical reliability.

Equation 2: Observed Composite Graft Survival Rate

$$Composite\ Graft\ Suvival\ Rate_{Observed\ Adjusted} = \frac{\#\ of\ Functioning\ Grafts\ +\ 2}{Total\ Completed\ Transplants\ +\ 2}$$

To enhance the statistical reliability of the composite graft survival rate, particularly for

IOTA participants with a small volume of kidney transplants, a +2 Bayesian adjustment will be applied to the observed composite graft survival rate. This is a form of statistical smoothing that addresses instability that occurs when calculating rates from small transplant volume numbers. For instance, at a kidney transplant hospital with very few kidney transplants, a single poor outcome can cause its observed survival rate to be an extreme and potentially misleading value (for example, 0 percent). This volatility can obscure the IOTA participant's true underlying performance. The +2 Bayesian adjustment helps correct this.

The adjustment works by adding two "pseudo-events" to each IOTA participant's actual data before calculating their composite graft survival rate. This technique prevents an IOTA participant's score from swinging dramatically based on just one or two outcomes. By implementing this Bayesian adjustment, the risk-adjustment model ensures that performance scores are more reliable across all IOTA participants, preventing smaller volume kidney transplant hospitals from being unfairly penalized due to random chance.

Next, CMS would calculate the risk score for each IOTA participant using the following equation (see Equation 3), which is a ratio that quantifies each IOTA participant's risk of graft failure relative to the national graft failure rate. It compares each IOTA participant's expected graft failure rate to the national graft failure rate.

Equation 3: Risk Score Equation

$$Risk\ Score = \frac{Expected\ Graft\ Failure\ Rate_{IOTA\ Participant}}{Graft\ Failure\ Rate_{National}}$$

A risk score greater than 1.0 indicates the IOTA participant's kidney transplant patients are estimated, on average, to have a higher risk of graft failure compared to the national graft failure rate. A risk score less than 1.0 means their kidney transplants are estimated, on average, to have a lower risk of graft failure. Multiplying the observed composite graft survival rate by the risk score (see Equation 6) adjusts the performance on this metric upward for IOTA participants taking on more risk and downward for IOTA participants with kidney transplants, on

average, with less risk of graft failure, allowing for a more equitable comparison of performance.

To calculate the expected graft failure rate needed for the risk score, CMS would use SRTR's adult kidney graft survival first-year, post-transplant risk-adjustment models for both deceased donor and living donor kidney transplants[51] which employs a Cox proportional hazards regression model to perform a time-to-event (TTE) analysis (see Equation 4).

Equation 4: Expected Graft Failure Rate.

$$Prob(failure) = 1 - S_0(t)exp^{(\beta X)}$$

In the equation for calculating the expected graft failure rate, $S_0(t)$ equals the baseline survival function and βX equals the linear predictor computed from SRTR's adult kidney graft survival first-year post-transplant risk-adjustment models variables and model coefficients. We note that this statistical approach is consistent with the core of the SRTR framework but by risk-adjusting the observed composite graft survival rate it has been adapted for the cumulative structure of the composite graft survival rate metric, as illustrated in Table 1.

TABLE 1: ADAPTATION OF SRTR'S RISK-ADJUSTMENT METHODOLOGY FOR THE IOTA MODEL

Feature	Standard SRTR Risk-Adjustment Model	IOTA Model's Adapted Risk-Adjustment Model
Primary Goal	Designed to generate distinct risk-adjusted graft survival rates over a specified, fixed period of time.	Adapts the SRTR framework to risk-adjust a cumulative observed composite graft survival rate on an ongoing basis for IOTA participants.
Time Horizon	Estimates the risk of graft failure at fixed, retrospective time points (for example, 1-year or 3-years post-transplant).	Estimates the risk of graft failure using SRTR's methodology for 1-year post-transplant
Core Methodology	Employs a TTE analysis using a Cox proportional hazards regression model.	Consistent with the core SRTR framework, it also uses a TTE analysis to calculate the expected graft failure rate needed for the risk score.
Variables Used	Uses a comprehensive and validated set of variables and coefficients for both deceased and living donors.	Maintains consistency by using SRTR's adult kidney graft survival first-year post-transplant models and most recently available set of variables and coefficients.
Final Output	Produces a standalone risk-adjusted graft survival rate for a specific cohort over a defined period (for example, 1-year graft survival rate).	Produces a risk score that is multiplied by the observed composite graft survival rate, thereby adjusting a cumulative metric rather than creating a new, period-specific one.

51 *https://www.srtr.org/transplant-professionals/program-specific-report/posttransplant-outcomes-risk-adjustment/*

This risk-adjustment methodology would use the most recently available comprehensive and validated set of risk factors and coefficients from SRTR's adult kidney graft survival first-year post-transplant risk-adjustment models for both deceased donor and living donor kidney transplants[52]. These include dozens of donor, transplant recipient, and transplant characteristics, such as donor and transplant recipient age, transplant recipient diabetes status, Calculated Panel Reactive Antibody (CPRA), Donation after Circulatory Death (DCD) status, cold ischemic time, and Kidney Donor Profile Index (KDPI) components. By using SRTR's established factors, the model aligns with commenters' requests for a robust, clinically validated system, and avoids issues identified in the initial proposal, such as the use of less reliable variables like estimated Glomerular Filtration Rate (eGFR) for dialysis patients. We note that we intend to analyze and monitor the variables and coefficients, and if analysis warrants updated coefficients, we may propose a new or updated policy through future comment and notice rulemaking as appropriate.

CMS would calculate the national graft failure rate for the relevant PY by dividing the number of graft failures, as defined by SRTR, among kidney transplants furnished to patients 18 years of age or older and performed during the given PY by the number of kidney transplants furnished to patients 18 years of age or older and performed during the given PY (see Equation 5). SRTR counts a graft as failed when follow-up information indicates that one of the following occurred before the reporting time point: (1) graft failure (except for heart and liver, when re-transplant dates are used instead); (2) re-transplant (for all transplants except heart-lung and lung); or (3) death.[53] CMS would identify graft failures in accordance with § 512.428(b)(1)(iv)(B). All kidney transplant hospitals, except for pediatric kidney transplant hospitals as defined at § 512.402, would be included in the numerator and denominator. By limiting both the numerator and denominator to kidney transplants performed during the relevant

52 https://www.srtr.org/transplant-professionals/program-specific-report/posttransplant-outcomes-risk-adjustment/
53 *Technical Methods for the Program-Specific Reports*. (n.d.). Www.srtr.org. Retrieved December 3, 2022, from https://www.srtr.org/transplant-professionals/program-specific-report/technical-methods-for-the-program-specific-reports/; OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics*. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf

PY, this calculation is temporally aligned with each IOTA participant's expected graft failure rate calculation, ensuring a consistent and comparable time horizon across both rates. Once calculated, the resulting amount is the national graft failure rate for kidney transplants performed for the relevant PY. The risk score would be normalized to provide a national mean of 1.0.

Equation 5: National Graft Failure Rate.

$$National\ Average\ Graft\ Failure\ Rate\ = \frac{Number\ of\ Graft\ Failures}{Number\ of\ Completed\ Kidney\ Transplants}$$

Lastly, the risk-adjusted composite graft survival rate for an IOTA participant would be calculated by multiplying its observed composite graft survival rate by a calculated risk score (see Equation 6). This approach maintains the risk-adjusted composite graft survival rate metric as an intuitive survival rate, directly adjusted for expected graft failure risk.

Equation 6: Composite Graft Survival Rate Risk-Adjusted

$$Composite\ Graft\ Suvival\ Rate_{Rsk\ Adj}$$

$$= Composite\ Graft\ Survival\ Rate_{Observed\ Adjusted}\ x\ Risk\ Score$$

We clarify that, in the risk-adjustment methodology that we are finalizing and as described above, CMS would not round any numerical values derived from any of the calculations.

The following simplified example demonstrates how the risk-adjustment methodology works for two IOTA participants in PY2, IOTA participant A and IOTA participant B:

- Calculate observed composite graft survival rate. Table 2 contains the example number of kidney transplants, and the observed and adjusted graft survival rates.

TABLE 2: EXAMPLE OF OBSERVED AND ADJUSTED GRAFT SURVIVAL CALCULATIONS

Step	Calculation	IOTA Participant A	IOTA Participant B
1 – Identify total number of functioning grafts	N/A	82	88
2 – Identify total number of completed kidney transplants	N/A	100	100
3 – Calculate observed composite graft survival rate	Equation 1 to Paragraph (b)(1) at § 512.428	0.820	0.880
4 – Calculate observed composite graft survival rate with Bayesian adjustment	Equation 1 to Paragraph (b)(2)(ii)(A) at § 512.428, as illustrated in Equation 2	0.823	0.882

- Calculate Risk Score: Using SRTR's adult kidney graft survival first-year post-

transplant risk-adjustment models for both deceased donor and living donor kidney transplants[54], we compute the expected 1-year graft survival rates for IOTA participant A and IOTA participant B as well as the national 1-year graft survival rate, and the risk score for each IOTA participant, as illustrated in Table 3.

TABLE 3: EXAMPLE OF CALCULATION OF RISK SCORES

Step	Calculation	IOTA Participant A	IOTA Participant B
4 – Calculate expected graft failure rate	Equation 1 to Paragraph (b)(2)(ii)(B)(1)(i) at § 512.428, as illustrated in Equation 3.	0.145	0.158
5 – Calculate national graft failure rate	Equation 1 to Paragraph (b)(2)(ii)(B)(2)(i) at § 512.428, as illustrated in Equation 4.	0.150	0.150
6 – Calculate Risk Score	Equation 1 to Paragraph (b)(2)(ii)(B)(3) at § 512.428, as illustrated in Equation 5.	0.967	1.053

- Composite Graft Survival Rate Risk-Adjusted Calculation: As illustrated in Table 4, the composite graft survival risk rate risk-adjusted score would be calculated by using the risk score, calculated in step 2, to risk-adjust the Bayesian-adjusted observed composite graft survival rate (see Table 2, step 4) that was calculated in step 1 to arrive at the risk-adjusted composite graft survival rate, as illustrated in Table 4, step 7. In this example, the final risk-adjusted composite graft survival rate: 0.824 (observed composite graft survival rate) × 0.967 (risk score) = 0.797 for IOTA participant A, and 0.882 (observed composite graft survival rate) × 1.053 (risk score) = 0.929 for IOTA participant B.

TABLE 4: EXAMPLE RISK-ADJUSTED COMPOSITE GRAFT SURVIVAL RATE

Step	Calculation	IOTA Participant A	IOTA Participant B
7 – Calculate risk-adjusted composite graft survival rate	Equation 1 to Paragraph (b)(2)(ii)(C) at § 512.428, as illustrated in Equation 6	0.797	0.929

Initially, IOTA participant B (88 percent composite graft survival rate) appeared to perform better than IOTA participant A (82 percent composite graft survival rate). However, after risk-adjustment, the difference is amplified. IOTA participant A's performance is adjusted

54 https://www.srtr.org/transplant-professionals/program-specific-report/posttransplant-outcomes-risk-adjustment/

downward because its kidney transplants had lower-than-average risk (risk score < 1.0), meaning a higher survival rate was expected given its patient mix. IOTA participant B's strong performance is adjusted upward because it was achieved with higher-risk kidney transplants. The final risk-adjusted composite graft survival rate provides a more equitable basis for comparing performance.

We note that while this approach adapts elements from the SRTR framework rather than fully replicating its hierarchical model, it establishes a necessary baseline consistent with the IOTA Model's measure structure, as illustrated in Table 1. We intend to monitor IOTA participant performance under this methodology and, if necessary, propose a new or updated policy in future comment and notice rulemaking.

Comment: A commenter recommended that CMS forgo the inclusion of a risk-adjustment methodology in the calculation of the composite graft survival rate altogether, advocating for the exclusion of any risk-adjustment for donor and recipient characteristics. The commenter stated that, due to the cumulative year-over-year nature of the metric, the inclusion of risk-adjustment may have limited impact on results, particularly in later PYs.

Response: We thank the commenter for their feedback and for their perspective on the role of risk-adjustment in the composite graft survival rate metric. However, we respectfully disagree with the commenter's recommendation to forgo risk adjustment for donor and recipient characteristics.

We continue to believe that risk adjustment is an essential component of fair and meaningful performance measurement. Graft survival outcomes are influenced by a range of clinical factors related to both donors and recipients that are independent of care quality. Without appropriate risk adjustment, IOTA participants that serve more medically complex patient populations or accept higher-risk organs may be disproportionately penalized, which could create unintended incentives to avoid such cases.

We acknowledge the commenter's point that the cumulative, year-over-year structure of

the measure may moderate the impact of risk-adjustment over time. However, we believe that incorporating risk-adjustment remains important across all PYs to ensure that comparisons reflect differences in care rather than underlying patient or donor characteristics.

For these reasons, we are finalizing the inclusion of a risk adjustment methodology for the composite graft survival rate, as described in comment responses noted previously in this section, to support equitable comparisons and align incentives with the model's goals of improving access and outcomes in kidney transplantation.

Comment: Numerous commenters expressed opposition to the risk-adjustment methodology as proposed in the 2025 Proposed Rule, raising concerns similar to those described elsewhere in this section. Several commenters stated that the proposed methodology includes variables that are not routinely collected, clinically validated, or commonly used in transplant practice, may lack appropriate weighting for risk factors, and omits important validated variables. For example, a commenter stated that developing risk-adjustment methodologies is inherently complex and dynamic and expressed concern that the regulatory process may not be well suited for this purpose. This commenter also suggested that a simplified risk-adjustment approach could be susceptible to manipulation, potentially influencing patient and donor selection practices. Another commenter expressed concern that, because only a subset of eligible kidney transplant hospitals participate in the IOTA Model, a model specific to IOTA participants may not reflect national risk patterns.

In the context of alternative considerations, several commenters stated that the proposed methodology may not adequately capture the full range of donor and recipient risk and may lack key variables necessary for accurate modeling. These commenters also noted the existence of established and validated frameworks, such as those developed by OPTN and SRTR, and questioned the need for a separate risk-adjustment approach within the IOTA Model.

Response: We thank the commenters for their comprehensive and detailed feedback on the risk-adjustment methodology proposed for inclusion in the composite graft survival rate

calculation in the 2025 Proposed Rule (90 FR 57605). We carefully considered the technical, clinical, and operational concerns raised, including those related to variable selection, model validity, implementation complexity, and alignment with existing transplant frameworks.

As described in comment responses noted previously in this section, we are not finalizing the risk-adjustment methodology as proposed. Instead, we are finalizing an updated risk-adjustment methodology for the composite graft survival rate that is based on an adapted SRTR framework and tailored to align with the composite structure of the IOTA measure. This approach reflects our effort to balance the need for methodological rigor with operational feasibility and clinical relevance.

We believe that this adapted SRTR-based risk-adjustment methodology leverages an established and widely used framework that has been developed with extensive clinical expert input and is subject to ongoing validation, recalibration, and refinement. By building on this foundation, we are able to incorporate clinically validated donor and recipient characteristics that are known to influence graft survival independent of care quality, while avoiding the need to develop a wholly new and untested methodology.

Additionally, we believe that aligning with an established framework supports greater consistency with existing transplant evaluation systems and reduces potential confusion or burden for IOTA participants, who may already be familiar with SRTR-based approaches. At the same time, adapting the methodology to the composite structure of the IOTA measure allows us to address the unique design considerations of the model, including its rolling measurement approach and performance year structure.

Overall, we believe this updated risk-adjustment methodology improves the accuracy, fairness, and interpretability of the composite graft survival rate measure by ensuring that performance differences more appropriately reflect variation in quality of care rather than underlying patient or donor risk profiles.

Comment: Some commenters expressed concerns about risk-adjustment implementation,

including concerns about risk aversion, complexity, and update frequency. In the context of the alternatives considered, a commenter specifically recommended that CMS prioritize stability in the risk-adjustment approach during the model performance period, suggesting the use of a limited set of clearly defined risk-adjusters with fixed effects across the model performance period, such as donor type, patient age, dialysis duration, and diabetes status, to allow IOTA participants to make informed operational and clinical decisions. This commenter further noted that frequent methodological changes during a model performance period may create uncertainty and reduce the ability of IOTA participants to respond effectively to model incentives.

Response: We thank the commenters for their feedback regarding the implementation of the risk-adjustment methodology in the composite graft survival calculation, including concerns related to potential risk-averse behavior, methodological complexity, and the frequency of updates. We also appreciate the recommendation to prioritize stability during the model test period through the use of a limited set of fixed risk-adjustment factors to support informed operational and clinical decision-making.

As mentioned in comment responses noted previously in this section, we are finalizing a modified methodology, in response to public comments, we are finalizing a modified risk-adjustment methodology for the composite graft survival rate calculation that is designed to balance clinical validity, methodological rigor, and operational feasibility. Specifically, the finalized approach leverages an adapted SRTR-based risk-adjustment framework that incorporates a comprehensive and clinically validated set of donor and recipient characteristics and aligns with the cumulative structure of the IOTA measure.

We acknowledge concerns that risk-adjustment may incentivize risk-averse behavior. However, we believe that incorporating a robust risk-adjustment methodology is essential to ensure fair comparisons across IOTA participants and to mitigate disincentives for accepting higher-risk organs or treating more complex patients. By adjusting for expected differences in graft failure risk, the methodology supports equitable performance assessment and aligns with

the model's goal of expanding transplant access.

We also recognize concerns regarding complexity. While we considered a more limited set of fixed risk-adjustment factors, we believe that such an approach would not sufficiently capture the full range of donor and recipient risk and could reduce the accuracy and fairness of the measure. By leveraging the established SRTR framework, which is widely used and familiar to transplant programs, we believe the finalized methodology appropriately balances complexity with usability while relying on clinically validated variables.

With respect to stability and update frequency, we agree that predictability is important for IOTA participants. To address this, the methodology we are finalizing uses the most recently available validated SRTR variables and coefficients and does not introduce frequent or ad hoc methodological changes. We note that we intend to analyze and monitor the coefficients, and if analysis warrants updated coefficients, we would propose a new or updated policy through future comment and notice rulemaking, thereby providing transparency and stability during the model performance period.

Finally, we note that we have incorporated features to improve reliability and reduce unintended variability, including a Bayesian adjustment to stabilize performance for lower kidney transplant volume IOTA participants. We believe that this approach helps ensure that performance scores are not disproportionately influenced by small sample sizes and supports more consistent and actionable results for IOTA participants. Additionally, we will analyze and monitor the performance of IOTA participants to assess the impact of this policy. If our analysis indicates the possible need for a new or revised policy, we will consider addressing it through future notice and comment rulemaking. We also intend to analyze and monitor SRTR's variables and coefficients, and if analysis warrants updated variables or coefficients, we would propose a new or updated policy through future comment and notice rulemaking, thereby providing transparency and stability during the model performance period.

For these reasons, we believe the risk-adjustment methodology that we are finalizing

appropriately addresses commenters' concerns while maintaining a robust, equitable, and stable framework that enables IOTA participants to respond effectively to model incentives and supports the model's goals of improving kidney transplant access and outcomes.

Comment: Many commenters opposed the proposed risk-adjustment methodology, raising significant concerns about its design and urging CMS to reconsider or adopt an alternative approach. These commenters stated that the methodology lacked sufficient clinical input and had not been adequately validated for use in the transplant population. Some of these commenters raised concerns about how frequently variables and coefficients would be updated and whether the methodology would remain aligned with evolving clinical practice.

Separately, some commenters expressed concerns regarding the implementation of risk-adjustment. Several noted that any risk-adjustment methodology, including SRTR's, could incentivize IOTA participants to be more cautious in accepting higher-risk organs or patients. A few commenters also highlighted the complexity of the SRTR methodology and the potential need for additional education and resources to support its interpretation. A commenter questioned whether risk-adjustment would meaningfully affect a cumulative measure over time, particularly in later performance years.

Response: We thank the commenters for their feedback regarding the proposed risk-adjustment methodology, including concerns related to clinical input and validation, implementation complexity, potential for risk-averse behavior, the cumulative nature of the measure, and update frequency. We note that we are not finalizing the proposed risk-adjustment methodology and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework, as described in previous comment responses in this section. We direct readers to comment responses noted previously for further discussion.

Comment: Numerous commenters identified what they believe were technical errors in the proposal, including the misidentification of "PRA" as "plasma renin activity" rather than "Panel Reactive Antibody," a measure of the percentage of cells from a panel of donors with

which a transplant candidate's serum reacts, indicating the degree of sensitization to potential donor antigens, and the incorrect inclusion of donor PRA when PRA only applies to recipients. Several commenters also provided detailed explanations of what PRA actually measures and its clinical significance in transplant matching. A few commenters further noted that the current standard in transplant medicine has largely moved to CPRA, which provides a more precise measure of sensitization, and recommended that CMS update its terminology accordingly. Commenters also stated that PRA is clinically relevant only for transplant recipients, not organ donors. Many commenters also provided detailed clinical explanations, noting that donor organs neither transmit nor synthesize donor-specific antibodies in response to antigen exposure, such that measuring a panel of reactive antibodies in an organ donor is not clinically indicated. Some commenters further stated that the inclusion of donor PRA in the proposed methodology reflects a fundamental misunderstanding of transplant immunology.

Response: We appreciate the detailed clinical explanations provided by commenters and agree with this feedback. Subsequent to the publication of the 2025 Proposed Rule, we acknowledge that we inadvertently used; we clarify that the term that should have been used was Panel Reactive Antibody (PRA) levels. We note that we are not finalizing the proposed risk-adjustment methodology, as described in this section of this final rule, and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework, as described in previous comment responses in this section. We direct readers to comment responses noted previously for further discussion.

Comment: Several commenters noted that the proposed risk-adjustment methodology for inclusion in the composite graft survival rate calculation included donor and transplant recipient variables that are not routinely collected, are difficult to define consistently, or are inappropriate for the intended purpose. Specifically, commenters stated that using eGFR and creatinine for dialysis patients is problematic because these values reflect dialysis clearance rather than native kidney function, and creatinine values can fluctuate post-dialysis. They also identified variables

such as "diabetes status" and "hypertension with or without cardiovascular disease" as not being consistently documented, subject to varied interpretation, and not currently reported to the OPTN, which would necessitate additional data collection. Finally, commenters identified what they believed were important clinical variables omitted from the proposed methodology and recommended additional variables for inclusion.

In the context of the alternative considerations, several commenters provided additional specific recommendations, including retransplant status, APOL1 genotype, donor viral studies, prior national organ turndowns (rescue allocation pathways), body mass index (BMI), warm ischemic time, normothermic regional perfusion (NRP) use, and socioeconomic factors.

Response: We thank the commenters for their feedback and acknowledge the concerns raised regarding the proposed risk-adjustment methodology. As described in comment responses noted previously in this section, we are not finalizing the proposed risk-adjustment methodology. Instead, we are finalizing an updated risk-adjustment methodology for the composite graft survival rate calculation that is based on an adapted SRTR framework and aligned with the cumulative structure of the metric. By leveraging SRTR's established variables and coefficients, we believe the finalized approach aligns with commenters' requests for a robust, clinically validated methodology and addresses issues identified in the proposal, including the use of less reliable or inconsistently defined variables such as "eGFR" for dialysis patients. We direct readers to comment responses noted previously in this section for further discussion of these changes and our rationale.

Comment: Some commenters identified clinical variables they considered to be significant omissions from the proposed risk-adjustment methodology, citing peripheral vascular disease, serum albumin, dialysis duration, time on waitlist, cold ischemic time, functional status, Kidney Donor Profile Index (KDPI) or its individual components, donor type (including living, deceased, and donation after circulatory death), and ischemic cardiac disease. Many commenters noted that these variables are incorporated into established models for well-documented clinical

reasons and have been validated as meaningful predictors of transplant outcomes. Several commenters further recommended the inclusion of additional variables, such as retransplant status, APOL1 genotype, donor viral studies, prior national organ turndowns (that is, rescue allocation pathways), BMI, warm ischemic time, normothermic regional perfusion (NRP) use, and socioeconomic factors including insurance status, education level, and employment. A commenter recommended the incorporation of individual KDPI components rather than aggregate scores to enhance methodological transparency. Another commenter suggested the inclusion of the kidney transplant recipient's geographic accessibility to the kidney transplant hospital in order to account for access and transportation challenges encountered in the post-transplant period, particularly among patients residing in rural areas.

Response: We thank the commenters for their feedback regarding clinical variables they identified as omitted from the proposed risk-adjustment methodology. We acknowledge the importance of incorporating clinically relevant and validated predictors of transplant outcomes. As described in comment responses noted previously in this section, we are not finalizing the proposed risk-adjustment methodology and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework. This approach incorporates a comprehensive set of clinically validated donor and recipient characteristics and reflects established consensus within the transplant community regarding appropriate risk-adjustment factors. We believe that leveraging the SRTR-based risk-adjustment methodology addresses many of the concerns raised by commenters regarding omitted variables while supporting a robust and clinically grounded approach to performance measurement. We direct readers to comment responses noted previously in this section for further discussion of these changes and our rationale.

Comment: Commenters noted problems with using (eGFR) and creatinine for risk-adjustment. Commenters stated that eGFR is not useful for patients on dialysis, as most transplant candidates are dialyzed and the value reflects dialysis clearance rather than native

kidney function. Several commenters noted that creatinine fluctuates post-dialysis and does not accurately reflect kidney function for risk-adjustment purposes. Some commenters also noted that eGFR can be artificially elevated if the transplant candidate was on dialysis, rendering these values misleading for risk assessment. A commenter specifically noted that a transplant candidate may be in acute renal failure and on dialysis, with measured serum creatinine and therefore eGFR appearing within normal range, but purely as an artifact of dialysis machine function rather than actual kidney function. Another commenter suggested that CMS incorporate BMI into its kidney function measurement, as creatinine levels carry different clinical meanings for individuals with varying BMIs.

Response: We thank the commenters for their feedback regarding the elements included in the risk-adjustment methodology. We note that we are not finalizing the proposed risk-adjust methodology, as described in this section of this final rule, and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework, as described in previous comment responses in this section, which includes eGFR and BMI. We direct readers to comment responses noted previously for further discussion.

Comment: Many commenters requested greater transparency regarding the proposed risk-adjustment methodology, including the publication of specific equations, model coefficients, variable definitions, and weighting approaches. Commenters stated that without this information, IOTA participants may not be able to fully understand how performance is evaluated or take meaningful steps to improve outcomes. Several commenters further recommended that CMS provide a detailed methodological description and allow for public comment prior to implementation. These commenters suggested that CMS develop and evaluate multiple alternative risk-adjustment models, empirically identify variables for inclusion, validate each approach, and make comparative results publicly available. In addition, a commenter noted that without transparency into the risk-adjustment methodology, including variable selection, weighting, and update frequency, IOTA participants may have limited ability to monitor

performance or respond effectively to model incentives.

Response: We appreciate this concern and recognize the need for transparency. To address the comments we received regarding providing transparency in describing how the risk-adjustment methodology in the calculation of the composite graft survival rate is calculated and applied so they can understand and track their kidney transplant hospitals' performance, we intend to provide sub-regulatory guidance on the technical specifications for calculating the inclusion of the risk-adjustment methodology in the composite graft survival rate calculation. We thank the commenters for their feedback regarding the proposed risk-adjustment methodology.

Comment: Several commenters expressed concern about the lack of data review and correction process. Commenters noted that SRTR allows transplant hospitals to review and correct data before public reporting, and that incomplete or inaccurate data, particularly data originating from OPOs, could compromise the accuracy of risk-adjustment under the proposed approach. Several commenters specifically requested that IOTA participants be permitted to review, complete, or correct donor and recipient data used for the risk-adjustment model, noting that OPOs frequently submit incomplete data that negatively impacts the accuracy of an IOTA participant's risk-adjustment. Commenters also requested clarification on how donor and recipient data will be obtained and validated and expressed concern about the absence of a formal hospital review and correction process.

Response: We thank the commenters for their feedback. We note that we are not finalizing the proposed risk-adjustment methodology, as described in this section of this final rule, and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework, as described in previous comment responses in this section. We note that in accordance with § 512.422(b), we will utilize data that is available when we calculate final performance scores for a given PY in accordance with § 512.430(d). We direct readers to comment responses noted previously for further discussion.

Comment: Several commenters expressed concern that using a different risk-adjustment methodology for IOTA than SRTR could create conflicting performance standards. Commenters explained that IOTA participants could perform well in the IOTA Model but poorly under SRTR metrics, potentially threatening their COE status, a designation used by commercial payers to determine network participation, preferred reimbursement arrangements, and referral eligibility. Since commercial transplant volume often exceeds Medicare FFS volume for many IOTA participants, commenters stated that the financial risk of losing COE status could exceed any IOTA Model payments. Commenters noted that this could cause IOTA participants to prioritize protecting their SRTR standings over the IOTA Model goals, potentially reducing overall kidney transplant volume contrary to the IOTA Model's goals. Commenters provided specific examples of how this misalignment could affect IOTA participants, noting that loss or degradation of SRTR performance can have material downstream consequences, including loss of COE designation, termination or non-renewal of commercial contracts, reduced referrals from employer-sponsored and managed care plans, and significant decreases in commercial transplant volume. Commenters also noted that the existence of two differing risk-adjusted methodologies would undermine the goal of increased kidney transplants, as IOTA participants would continue to prioritize SRTR outcome measures to protect most of their patient contracts.

Response: We thank the commenters for their feedback regarding the proposed risk-adjustment methodology, including concerns related to using a different risk-adjustment methodology for the IOTA Model than the SRTR; however, we respectfully disagree. We recognize the importance of COE designations, which are quality tiers used by commercial health insurers to steer patients to top-performing kidney transplant hospitals. We also recognize that MA plans operate similarly, frequently using COE or preferred facility networks to determine network participation for MA beneficiaries.

We understand the commenters' concern that if the IOTA Model and SRTR used completely different risk-adjustment formulas, IOTA participants could face conflicting

incentives that might negatively impact their SRTR metrics, thereby risking their COE status and access to commercial and MA patients. However, we do not believe participating in the IOTA Model will jeopardize an IOTA participant's COE status or MA network inclusion. Insurers and MA plans evaluate a comprehensive array of metrics—generally post-transplant outcomes and some minimum number of kidney transplants, rather than a single SRTR data point—when determining network participation.

Furthermore, as described in comment responses noted previously in this section, we are not finalizing the proposed risk-adjustment methodology and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework. Because the IOTA risk-adjustment methodology is adapted directly from the SRTR framework, the metrics are highly aligned, largely eliminating the risk of conflicting performance standards. We direct readers to comment responses noted previously in this section for further discussion of these changes and our rationale, and to the 2024 Final Rule for further discussion on COE designations.

Comment: Some commenters sought clarification regarding the frequency with which the proposed risk-adjustment methodology would be updated and reweighted. Commenters noted that SRTR updates its models on a semi-annual basis and requested information on how these updates would be incorporated into the IOTA Model's annual performance assessments. A commenter specifically asked whether CMS intends to update risk-adjustment variables and beta coefficients on a rolling basis and requested additional explanation of the methodology used for such updates. Another commenter recommended that CMS collaborate with SRTR to evaluate time-to-event approaches using national data and clinical expertise to support statistical validity and patient-centered reporting.

Response: We appreciate these comments. We note that we are not finalizing the proposed methodology and are instead finalizing an updated risk-adjustment methodology based on an adapted SRTR framework using SRTR's adult kidney graft survival first-year post-transplant models for both deceased donor and living donor kidney transplants and most recently

available set of variables and coefficients. As such, we believe the risk-adjustment methodology that we are finalizing, as described in comment responses noted previously in this section, appropriately addresses the request for clarity SRTR's methodology updates variables and coefficients on a rolling basis. We direct readers to comment responses noted previously in this section for further discussion of these changes and our rationale.

Comment: Some commenters raised concerns about what they characterized as the misalignment between CMS's approach to measuring and incentivizing transplant hospital performance under the IOTA Model and its approach to regulating OPO performance under the Conditions for Coverage (CFC) Final Rule. Commenters described the CFC framework as evaluating OPOs against unadjusted, relative performance thresholds, without adjustments for performance improvement, donor complexity, or case mix. Commenters argued that this divergence is particularly striking given CMS's explicit recognition in the 2025 Proposed Rule that donor and recipient characteristics materially affect transplant outcomes and therefore warrant risk-adjustment for transplant hospital performance measures. Commenters stated that CMS's continued position that similar donor-related factors do not warrant risk-adjustment for OPO performance metrics is difficult to reconcile with the agency's stated rationale for risk-adjustment under the IOTA Model and undermines system-wide coherence in the regulation of the donation and transplantation system.

Response: We appreciate the commenter's feedback; however, we do not believe that it is appropriate to directly compare the performance metrics of OPOs and kidney transplant hospitals. Both OPOs and kidney transplant hospitals have unique roles in the transplant ecosystem, requiring different focuses, skills sets and responsibilities. We acknowledge the different responsibilities of these two parties along the continuum of care for organ transplantation. Overall, performance metrics are meant to understand current state, to set goals to create improvement, to ensure unintended consequences of changes are identified, and to allow for analysis and evaluation to pivot and modify metrics when appropriate. With

overarching goals to improve kidney transplant volume while maintaining quality organs and patient care, we do not believe that CMS has misaligned goals in its different approaches to OPOs and kidney transplant hospitals.

Comment: Some commenters raised concerns about the potential impact of the proposed risk-adjustment methodology on smaller and rural kidney transplant hospitals. Commenters noted that, with only half of all eligible kidney transplant hospitals enrolled in IOTA, a model unique to IOTA participants may not represent true national risk and requested clarification on whether IOTA participant performance would be benchmarked against IOTA participants only or against all kidney transplant hospitals nationally. A commenter noted that for small or rural IOTA participants, the impact of performance scoring is particularly significant, as the commenter believed there are insufficient quality organ offers to sustain current volume without the growth goals imposed by CMS, and that increasing kidney transplant volume is not feasible when suitable organs are not available.

Response: We appreciate the comments. We recognize that it can be more difficult for rural patients to receive a kidney transplant. However, we believe that the raising of the low volume threshold to 15 kidney transplants performed annually during each of the baseline years, as described and finalized in section II.B.1.b of this final rule, should remove the lowest-volume kidney transplant hospitals that would be at most risk from any impact from the IOTA Model. Additionally, to directly address concerns regarding the reliability of performance scoring for smaller volume IOTA participants, our risk-adjustment methodology incorporates a +2 Bayesian adjustment. This statistical safeguard is specifically intended to avoid instability in calculating rates from small kidney transplant volumes, ensuring that a limited number of adverse outcomes do not cause disproportionate swings in an IOTA participant's performance score. Finally, we note that performance in the achievement domain is measured based on each IOTA participant's individual historic kidney transplant volume, meaning that an IOTA participant will not need to greatly exceed its own already demonstrated capacity.

Comment: A commenter urged CMS to clarify that the term "living donor" within the proposed definition of single-organ kidney transplant is not limited to human donors and is sufficiently broad to encompass xenotransplant organs (animal-to-human transplants) once such products receive FDA approval and become commercially available. The commenter noted that should the definition be interpreted as limited exclusively to human donors, xenotransplant procedures may not be counted toward transplant volume in the IOTA achievement domain. Given that participation in the IOTA Model is mandatory for approximately half of all eligible kidney transplant hospitals, the commenter suggested that the exclusion of these products would effectively disincentivize IOTA participants from adopting innovative solutions to address the organ shortage. The commenter further expressed the view that if xenotransplant procedures are not included in performance calculations tied to financial incentives, IOTA participants may be financially discouraged from utilizing these life-saving products when available, thereby undermining the model's primary objective of increasing access to care. As such, the commenter recommended that CMS explicitly clarify that the definition of single-organ kidney transplant is not limited to human organs and could include xenotransplant organ products upon FDA approval and commercial availability.

Response: We thank the commenter for their feedback and for requesting clarification regarding whether the term “living donor” within the definition of single-organ kidney transplant should encompass xenotransplantation (animal-to-human transplants) upon FDA approval and commercial availability. We acknowledge the commenter’s interest in ensuring that emerging technologies are appropriately considered within the IOTA Model.

At this time, xenotransplant organs are not FDA approved or available for kidney transplantation. We believe that establishing policy for technologies that are not yet approved would introduce unnecessary complexity and uncertainty into the model. We also note that FDA approval alone would not necessarily indicate that xenotransplant procedures should be treated identically to human organ transplants for purposes of performance measurement and payment.

The IOTA Model's quality measures, including graft survival, are based on extensive historical data from human organ transplants. Xenotransplantation may involve different clinical characteristics, including variations in survival rates, rejection patterns, immunosuppression requirements, and long-term outcomes, which could complicate fair and meaningful performance comparisons across IOTA participants if included under the same metrics.

For these reasons, we do not believe the definition of single-organ kidney transplant should be revised to explicitly address xenotransplant products at this time, and we will finalize this definition without modification. However, we will continue to monitor advancements in this area and may consider future policy updates, as appropriate, through future notice and comment rulemaking, should xenotransplantation receive FDA approval and become clinically established and relevant to the IOTA Model.

Comment: Some commenters expressed support for CMS's proposal 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. Commenters acknowledged that multi-organ transplant procedures entail substantially different care processes, heightened clinical complexity, and outcome expectations that differ significantly from those associated with kidney-only transplants. Some of these commenters further noted that the limited population of multi-organ transplant recipients presents considerable challenges for adequate risk-adjustment, and that such complex cases carry an elevated risk of outlier outcomes that could unduly impact IOTA participants' performance scores.

Response: We thank the commenters for their support of our proposal to exclude multi-organ transplants, with the exception of kidney/pancreas transplants, from the numerator and denominator when calculating the composite graft survival rate in the quality domain. We agree that multi-organ transplant recipients represent a clinically distinct population with unique care requirements and outcome trajectories that differ from those of kidney-only transplant recipients.

We additionally recognize that the inherent clinical complexity of multi-organ

transplantation, combined with the relatively limited number of such procedures performed, presents considerable challenges for developing robust risk-adjustment methodologies that would permit fair and accurate performance comparisons across IOTA participants. However, we believe excluding multi-organ transplants except for kidney/pancreas transplants from the numerator and denominator when calculating the composite graft survival rate enhances the validity of the measure by ensuring that performance assessments more accurately reflect outcomes pertaining to kidney transplantation, without the confounding influence of additional organ involvement or the unique physiological considerations associated with multi-organ procedures. We further believe this policy supports the IOTA Model's objectives of promoting increased transplant access while maintaining appropriate quality standards. For these reasons, we are finalizing our provision to exclude multi-organ transplants except for kidney/pancreas transplants from the numerator and denominator when calculating the composite graft survival rate without modification.

Comment: A commenter noted that multi-organ transplants are more commonly performed at higher-volume kidney transplant hospitals and expressed concern that the continued inclusion of kidney/pancreas transplants could place IOTA participants with active kidney/pancreas transplant programs at a disadvantage relative to those who perform few or no kidney/pancreas transplants.

Response: We thank the commenter for raising this concern. We recognize that multi-organ transplant procedures, including kidney/pancreas transplants, are often concentrated at larger, specialized transplant hospitals. As mentioned in comment responses noted previously in this section, we are finalizing this provision without modification. We note that, for kidney/pancreas transplants included in the composite graft survival rate, the measure evaluates kidney graft survival only. We believe this methodology addresses the concern that IOTA participants performing higher volumes of kidney/pancreas transplants could be disadvantaged relative to those performing fewer such procedures, as performance is assessed based on kidney

transplant outcomes rather than the volume or complexity of pancreas-related care. Additionally, consistent with § 512.428(b)(1)(iii)(E), the exclusion of other multi-organ transplants from the composite graft survival rate calculation further ensures that IOTA participants performing more complex procedures are not disproportionately affected in their overall performance scores. For these reasons, we believe the finalized approach supports fair and equitable comparisons across IOTA participants while maintaining focus on kidney transplant outcomes.

Comment: Some commenters noted that multi-organ transplants involve substantially different care processes and outcome expectations compared to single-organ kidney transplants. These differences include more complex perioperative management, different long-term challenges, and outcomes that are not comparable to those of otherwise similar single-organ kidney transplant recipients.

Response: We agree that multi-organ transplant recipients face substantially different care processes and outcome expectations compared to single-organ kidney transplant recipients. Perioperative management requires coordination across multiple surgical teams and medical specialties, and long-term care involves managing the function and potential complications of multiple transplanted organs simultaneously. We further agree that outcomes for multi-organ transplant recipients are not comparable to those of otherwise matched single-organ kidney transplant recipients, reflecting fundamental clinical distinctions inherent in multi-organ transplantation rather than differences in case mix alone, and therefore cannot be adequately addressed through risk-adjustment. We believe these differences directly support the policies we are finalizing at § 512.428(b)(1)(iii)(E) and 512.428(b)(1)(iv)(A). Specifically, § 512.428(b)(1)(iii)(E) excludes multi-organ transplants other than kidney/pancreas from the composite graft survival rate, ensuring that outcomes driven by non-kidney organ function do not confound the assessment of IOTA participant performance. For kidney/pancreas transplants included pursuant to § 512.428(b)(1)(iv)(A), measuring only kidney graft survival appropriately focuses the quality metric on kidney-specific care while acknowledging the additional

complexity of simultaneous kidney/pancreas transplantation.

Comment: Some commenters recommended that all multi-organ transplants, including kidney/pancreas transplants, should be excluded from the graft survival measure. These commenters cited significantly fewer offers for these patients, more restrictive donor acceptance criteria, and more complex post-transplant care requirements as justification for complete exclusion. Some commenters expressed concern that the continued inclusion of kidney/pancreas transplants in the metric has the potential to confound outcomes, place transplant hospitals with busy kidney/pancreas transplant programs at a disadvantage to their peers performing few or no kidney/pancreas transplants, and discourage IOTA participants from transplanting these patients. Additionally, a commenter noted that multi-organ transplants are likely to be performed predominantly at larger volume transplant hospitals and expressed concern that the continued inclusion of kidney/pancreas transplants could place IOTA participants with busy kidney/pancreas transplant programs at a disadvantage compared to their peers performing few or no kidney/pancreas transplants.

Response: We thank the commenters for raising their concern. We have carefully considered the recommendation to completely exclude kidney/pancreas transplants from the composite graft survival rate calculation. While we recognize the valid concerns raised about the clinical complexity and differential outcomes associated with these procedures, we believe that complete exclusion is not appropriate for several reasons. First, kidney/pancreas transplants represent a substantial volume of procedures at many transplant hospitals, and their complete exclusion could significantly reduce the sample size available for performance assessment at these transplant hospitals. Second, kidney/pancreas transplantation is an important treatment option for patients with both end-stage renal disease and diabetes, and complete exclusion from quality metrics could inadvertently discourage IOTA participants from offering this valuable service.

We also thank the commenter for raising the concern that the continued inclusion of

kidney/pancreas transplants could place IOTA participants with busy kidney/pancreas transplant programs at a disadvantage compared to their peers performing few or no kidney/pancreas transplants, which we carefully considered in evaluating alternatives. We recognize that kidney/pancreas transplants are often concentrated at larger, specialized transplant hospitals. We considered whether kidney/pancreas transplants should be excluded entirely from the composite graft survival rate, which would have fully eliminated the potential peer comparison disadvantage identified by the commenter. However, we determined that complete exclusion would reduce available sample sizes at high-volume transplant hospitals and could inadvertently discourage IOTA participants from offering this important treatment option. We therefore conclude that the most appropriate alternative is to include kidney/pancreas transplants while measuring only kidney graft survival. We believe this approach ensures that differences in kidney/pancreas transplant volume across IOTA participants do not create disparities in IOTA Model performance scores, as IOTA participants will not be penalized for pancreas-specific complications or failures that do not affect kidney graft function, thereby preserving a fair basis for peer comparison while maintaining consistency with the IOTA Model's focus on kidney transplant performance.

For these reasons, we are finalizing the policy to include kidney/pancreas transplants in the composite graft survival rate calculation, with only the kidney graft survival counted toward the quality metric. We believe this approach addresses the specific concerns raised by commenters while maintaining appropriate performance assessment for IOTA participants.

Comment: Some commenters acknowledged that developing appropriate risk-adjustment methodologies for multi-organ transplants would require rigorous analysis considering organ scarcity, dynamic decision making, and heterogeneous practice patterns. The complexity of creating fair and accurate risk-adjustment for these procedures was cited as a key reason supporting their exclusion from the composite graft survival rate calculation. A commenter specifically noted that while the total number of recipients of multi-organ transplants has grown

in recent years, the total number remains small relative to the total number of kidney transplants performed.

Response: We thank the commenters and agree that developing robust risk-adjustment methodologies for multi-organ transplants would require extensive analysis and would present significant methodological challenges. We believe heterogeneity in multi-organ transplant procedures, the relatively small number of cases performed annually, the wide variation in practice patterns across transplant hospitals, and the complex interplay between multiple organ systems in determining patient outcomes all contribute to the difficulty of creating risk-adjustment models that would allow for fair comparison of IOTA participant performance.

Given these challenges and the potential for risk-adjustment models to inadequately account for the full complexity of multi-organ transplantation, we are finalizing the policy to exclude multi-organ transplants (other than kidney/pancreas) from the composite graft survival rate calculation. For kidney/pancreas transplants, only the kidney graft survival will be counted toward the quality metric. We believe this decision allows us to focus quality assessment on kidney transplant performance using risk-adjustment methodologies that are better suited to the kidney transplant population and that can more accurately account for the relevant patient and donor characteristics affecting kidney graft survival. We intend to continue to monitor outcomes for all transplant types through existing oversight mechanisms and may consider future refinements to the IOTA Model based on additional data and stakeholder input as appropriate.

Comment: Some commenters noted that multi-organ transplants involve substantially different care processes and outcome expectations compared to single-organ kidney transplants. These differences include more complex perioperative management, different long-term challenges, and outcomes that are not comparable to those of otherwise matched kidney-alone recipients.

Response: We agree that multi-organ transplant recipients face substantially different care processes and outcome expectations compared to single-organ kidney transplant recipients,

including more complex perioperative management, different long-term challenges, and outcomes that are not comparable to those of otherwise matched single-organ kidney transplant recipients. We believe this last point carries important methodological implications: because outcome differences persist even after accounting for patient and donor characteristics, they cannot be adequately addressed through risk-adjustment alone. These clinical distinctions informed our evaluation of three primary alternatives: (1) including all multi-organ transplants with updated risk-adjustment; (2) excluding all multi-organ transplants, including kidney/pancreas; and (3) excluding most multi-organ transplants while retaining kidney/pancreas with a kidney-only outcome measure. We rejected the first alternative because the non-comparability of outcomes even among otherwise matched recipients confirms that risk-adjustment models designed for the kidney transplant population would be insufficient to support fair performance assessment. We rejected complete exclusion because, while supported by the clinical distinctions raised by commenters, it would unnecessarily reduce sample sizes and could discourage IOTA participants from offering kidney/pancreas transplantation. We therefore concluded that excluding multi-organ transplants other than kidney/pancreas from the composite graft survival rate, while retaining kidney/pancreas transplants with only kidney graft survival counted toward the quality metric, best accounts for the substantially different care processes and outcome expectations associated with multi-organ transplantation while maintaining meaningful quality assessment focused on kidney transplant performance.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the proposed definition of single-organ kidney transplant at § 512.402 without modification. Furthermore, we are finalizing our proposal 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 at proposed § 512.428(b)(1)(iii)(E) and 512.428(b)(1)(iv)(A) without modification.

In response to comments received, we are replacing the risk-adjustment methodology we had proposed to use for purposes of calculating performance on the composite graft survival rate in the quality domain. Specifically, we are codifying in our regulation at § 512.428(b)(2)(i) that in accordance with paragraphs (b)(1) through (3) of this section CMS risk-adjusts the composite graft survival rate using SRTR's adult kidney graft survival first-year outcomes variables in accordance with § 512.428(b)(2)(ii)(A) through (C).

We are codifying the risk-adjustment methodology for the composite graft survival rate that is based on an adapted SRTR framework in our regulation in sections § 512.428(b)(2)(ii)(A) through (C). Specifically, we are finalizing our regulation at § 512.428(b)(2)(ii)(A), that in accordance with § 512.428(b)(1), CMS calculates the observed composite graft survival rate by dividing the number of functioning grafts plus two by the total number of completed kidney transplants plus two as described in Equation 1 to paragraph (b)(2)(ii)(A) at § 512.428.

We are codifying the methodology for calculating the risk score for each IOTA participant in our regulation at § 512.428(b)(2)(ii)(B)(1) through (3). Under this provision, CMS calculates each IOTA participant's risk of graft failure relative to the national graft failure rate. We are finalizing at § 512.428(b)(2)(ii)(B)(1)(i) through (ii) that CMS calculates the expected graft failure rate using SRTR's methodology as described in Equation 1 to paragraph (b)(2)(ii)(B)(1)(i) at § 512.428 and SRTR's adult kidney graft survival first-year post-transplant risk-adjustment models for both deceased donor and living donor kidney transplants and the most available set of coefficients. We are also finalizing the methodology for calculating the national graft failure rate in our regulation at § 512.428(b)(2)(ii)(B)(2)(i) through (iv). Under this provision, CMS calculates the national graft failure rate by dividing the number of graft failures by the number of completed kidney transplants as described in equation 1 to paragraph (b)(2)(ii)(B)(2) at § 512.428. For the calculation of the national graft failure rate, we are codifying at § 512.428(b)(2)(ii)(B)(2)(ii) through (iv) the following inclusion and exclusion criteria, as outlined in Table 5.

TABLE 5: NATIONAL GRAFT FAILURE RATE CALCULATION INCLUSION AND EXCLUSION CRITERIA

Component	Inclusion Criteria	Exclusion Criteria
Numerator (# of graft failures)	• Graft failure based on OPTN adult kidney transplant recipient follow-up forms • Re-transplant • Death	• Patients under 18 years of age at time of transplant • Pediatric kidney transplant hospitals • Multi-organ transplants (except kidney/pancreas)
Denominator – Total # of kidney transplants	• Single-organ kidney transplants (as defined at § 512.402) • Kidney/pancreas transplants for patients 18 years of age and older at time of transplant	• Patients under 18 years of age at time of transplant • Pediatric kidney transplant hospitals • Multi-organ transplants (except kidney/pancreas)

We are also finalizing at § 512.428(b)(2)(ii)(B)(3) that CMS will calculate the risk score for each IOTA participant by dividing each IOTA participants' expected graft failure rate by the national graft failure rate for all kidney transplants as described in Equation 1 to paragraph (b)(2)(ii)(B)(3) at § 512.428.

Additionally, we are finalizing at § 512.428(b)(2)(ii)(C) the calculation of the risk-adjusted composite graft survival rate as described in Equation 1 to paragraph (b)(2)(ii)(C) at § 512.428. Under this provision, CMS will multiply the observed composite graft survival rate, as calculated under § 512.428(b)(2)(ii)(A), by the risk score calculated under § 512.428(b)(2)(ii)(B).

Lastly, because we are finalizing a risk-adjustment methodology in the calculation of the composite graft survival rate, as described and finalized at § 512.428(b)(2), we are updating the regulatory text at § 512.428(b)(1)(ii). Specifically, we are finalizing at § 512.428(b)(1)(ii) that, for all subsequent PYs, CMS will calculate each IOTA participant's cumulative composite graft survival rate using the methodology described in § 512.428(b)(1) and in accordance with the risk-adjustment methodology finalized at § 512.428(b)(2).

We believe that these revisions, taken together, establish a comprehensive and methodologically sound approach to calculating the composite graft survival rate that improves accuracy, enhances statistical reliability, and supports equitable comparisons across IOTA participants by accounting for differences in donor and recipient risk while maintaining consistency with established, clinically validated SRTR methodologies. We note that we will

analyze and monitor IOTA participant performance throughout the model performance period to ensure we do not unduly disadvantage IOTA participants. If analysis results warrant a new or updated policy, we will address it pursuant to future notice and comment rulemaking as appropriate.

(b) Calculation of Points

In the 2024 Final Rule (89 FR 96280) 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 6, 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 6: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Points Earned
80th Percentile ≤	20
60th ≤ and < 80th Percentile	18
40th ≤ and < 60th Percentile	16
20th ≤ and < 40th Percentile	14
10th ≤ and < 20th Percentile	12
< 10th Percentile	10

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).

As stated in the 2025 Proposed Rule, upon further review of our methodology, we proposed to modify the composite graft survival rate scoring methodology to allow for a more even scoring distribution for IOTA participants (90 FR 57609). Specifically, we proposed 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 7.

As described in the 2025 Proposed Rule, we proposed that points continue to be awarded based on national quintiles, as outlined in Table 7 (90 FR 57609). We maintained 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 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 recognized 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 proposed 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 7 (90 FR 57609):

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

- IOTA participants in the 20th to below the 40th percentile of performers, 5 points.
- IOTA participants who are below the 20th percentile of performers, 0 points.

TABLE 7: 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

As stated in the 2025 Proposed Rule, 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 (90 FR 57610). The scoring is normalized, meaning an average performing IOTA participant earns 10 points out of 20, 50 percent of the total possible points. We recognized 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 final rule, we proposed to incorporate a risk-adjustment methodology to the calculation of the composite graft survival rate measure. As such, we believed that the proposed allocation of points, as illustrated in Table 7, 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 final 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) (90 FR 57610). 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 7 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 recognized 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 (90 FR 57610). 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 proposed to incorporate a risk-adjustment methodology, as proposed in section II.B.2.(b).(2).(a). of the 2025 Proposed Rule, we believed that our proposed scoring approach rewards both achievement and improvements and is a more rigorous scoring methodology. Although we did not propose to include this alternative, we sought 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 sought 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 sought comments on alternatives considered.

Additionally, we sought 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).

The following is a summary of the comments we received on all of the calculation of points proposals and on the alternatives considered set out in this section and our responses:

Comment: Several commenters recommended that CMS incorporate an improvement component into the scoring methodology for the composite graft survival rate metric within the quality domain. Specifically, these commenters suggested a dual-scoring system whereby CMS would determine both an achievement score and an improvement score, subsequently awarding the point value equivalent to the higher of the two scores. Commenters noted that this approach would recognize IOTA participants demonstrating meaningful progress, even in instances where their absolute performance has not yet reached higher percentile thresholds.

Response: We appreciate commenters' suggestions regarding the inclusion of improvement scoring on the composite graft survival rate metric within the quality domain. As discussed at 90 FR 57610 in the 2025 Proposed Rule and in this section of this final rule, we considered applying a two-scoring system in which we would determine an achievement score and an 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 described at § 512.426(c). As described in the preamble of this section of this final rule, we considered applying a two-scoring system because we recognize that if an IOTA participant does not perform well in a given PY on the composite graft survival rate, it may be difficult for the IOTA participant to demonstrate meaningful improvement during the model performance period. We direct readers to section II.B.2.b.(2).(b). of this final rule for a full discussion on the two-scoring system methodologies we considered for calculating points on the composite graft survival rate.

Furthermore, we believe that the updated risk-adjustment methodology incorporated into

the composite graft survival rate calculation, as described and finalized in section II.B.2.b.(2).(a). of this final rule, inherently recognizes IOTA participants that improve their performance by accepting more complex cases, as changes in case mix complexity over time will be appropriately reflected. We also believe that the updated scoring methodology for performance on the composite graft survival rate, as outlined in Table 8 of this section of this final rule, rewards both achievement and improvement, constitutes a more rigorous scoring methodology, creates smoother transitions between scoring thresholds, and reduces the likelihood of a scenario in which a modest decrease in performance results in a disproportionate loss of points, as compared to the proposed approach as described in this section of this final rule.

However, we will continue to assess whether an improvement scoring methodology for performance on the composite graft survival rate metric in the quality domain would be appropriate for future PYs and will monitor IOTA participant performance to evaluate the feasibility of incorporating one. We remain interested in considering how an improvement scoring methodology could be incorporated into the composite graft survival rate and intend to conduct further analysis to evaluate the feasibility of incorporating a two-scoring system. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: Many commenters expressed concern that the proposed updates to the allocation of points for performance on the composite graft survival rate would create large performance "cliffs"[55] between scoring thresholds. Commenters noted that smaller kidney transplant hospitals may be disproportionately affected by these gaps due to greater statistical variability in their composite graft survival rates. Several commenters suggested more granular scoring thresholds, such as deciles, to reduce the impact of small variations in performance.

55 The cliffs mentioned by commenters refers to the “cliff effect” in scoring, a phenomenon where a small increase or decrease in performance results in a disproportionate gain or loss in points.

Response: We thank the commenters for expressing their concerns and for their suggestions on our proposed methodology for awarding points for the purpose of assessing performance on the composite graft survival rate in the quality domain. We acknowledge the concerns raised regarding the potential difficulties IOTA participants may face in achieving a top score on the composite graft survival rate metric. With respect to the concerns that a small number of adverse outcomes could significantly skew a kidney transplant hospital's data, we acknowledge that it is difficult to fully assess the extent to which such concerns may affect performance measurement across IOTA participants at this time, given the limited data currently available. However, we recognize there have been significant improvements in kidney transplantation outcomes over time due to advances in immunosuppressive therapies, surgical techniques, and organ preservation methods. We also recognize that post-transplant outcomes are already incentivized through private payers' COE programs and OPTN metrics.

We agree that the impact of statistical volatility is important, particularly for smaller IOTA participants. As such, in response to comments received, we are updating the methodology for the allocation of points for performance on the composite graft survival rate in the quality domain. Specifically, we are finalizing, with modification, Table 1 to paragraph (d) at § 512.428, to reflect the updated points allocation, as outlined in Table 8, such that IOTA participants that perform:

- IOTA participants in the 87.5th percentile of performers and above, 20 points.
- IOTA participants in the 75th to below 87.5th percentile of performers, 18 points.
- IOTA participants in the 62.5th to below 75th percentile of performers, 15 points.
- IOTA participants in the 50th to below 62.5th percentile of performers, 13 points.
- IOTA participants in the 37.5th to below 50th percentile of performers, 10 points.
- IOTA participants in the 25th to below 37.5th percentile of performers, 8 points.
- IOTA participants in the 12.5th to below 25th percentile of performers, 5 points.
- IOTA participants who are below the 12.5th percentile of performers, zero points.

TABLE 8: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
87.5th percentile	Equals 87.5th percentile	Greater than 87.5th percentile	20
75th percentile	Equals 75th percentile	Less than 87.5th percentile	18
62.5th percentile	Equals 62.5th percentile	Less than 75th percentile	15
50th percentile	Equals 50th percentile	Less than 62.5th percentile	13
37.5th percentile	Equals 37.5th percentile	Less than 50th percentile	10
25th percentile	Equals 25th percentile	Less than 37.5th percentile	8
12.5th percentile	Equals 12.5th percentile	Less than 25th percentile	5
12.5th percentile	N/A	Less than 12.5th percentile	0

We are adding additional thresholds where points will be based on national octiles, as illustrated in Table 8 in this section, rather than quintiles. We believe this approach reflects our partial agreement with commenters by providing greater granularity than both the current and proposed point allocation methodologies as described in this section of the final rule, while preserving greater simplicity than a full decile system comprising 10 thresholds. Furthermore, we believe that using 8 thresholds establishes smoother transitions between scoring thresholds, with increments of 2 or 3 points between most thresholds, thereby reducing the "cliff effect" identified by commenters. We believe this strikes an appropriate balance between granular performance differentiation and administrative feasibility.

Comment: Some commenters expressed concern that the proposal to assign zero points to IOTA participants falling below the 20th percentile is excessively punitive, particularly for safety-net hospitals and those serving high-risk populations and may serve as a disincentive for kidney transplantation even with risk-adjustment mechanisms in place.

Response: We appreciate commenters' concerns regarding the potential impact of awarding zero points to IOTA participants below the 20th percentile, particularly for safety-net hospitals serving vulnerable populations. We also recognize that risk-adjustment may not fully capture all challenges faced by safety-net hospitals. We believe the updated risk-adjustment methodology in the composite graft survival rate calculation, as described and finalized in section II.B.2.b.(2).(a). of this final rule, appropriately addresses case mix differences and ensures fair comparison across IOTA participants with varying patient populations. We also

believe that the updated scoring methodology for performance on the composite graft survival rate, as described and finalized in section II.B.2.b.(2).(b). of this final rule, reduces the likelihood of a scenario in which a small decrease in performance results in a significant loss of points, compared to the proposed approach, as described in this section of this final rule. We note that in the updated composite graft survival rate scoring methodology, as outlined in Table 8, zero points are awarded only to IOTA participants below the 12.5th percentile, rather than the 20th percentile as proposed. We believe that this update addresses the criticism of being overly punitive while balancing scoring granularity and administrative feasibility.

Comment: Some commenters requested that CMS establish minimum performance thresholds based on absolute quality standards for the composite graft survival rate rather than relative percentile rankings. Commenters suggested that IOTA participants should be able to meet objective benchmarks without being penalized simply for falling in the bottom percentile nationally, regardless of whether their absolute performance meets acceptable quality standards.

Response: We appreciate the commenters for their feedback and for raising the consideration of utilizing absolute quality standards for the composite graft survival rate. We acknowledge the concern that a purely relative, percentile-based scoring methodology for performance on the composite graft survival rate may result in IOTA participants being penalized despite achieving outcomes that could be considered acceptable from an absolute performance perspective.

We continue to believe that a relative, percentile-based methodology is appropriate for the purpose of allocating points for performance on the composite graft survival rate in the IOTA Model, as it enables comparison of performance across IOTA participants and supports the model's goal of driving continuous quality improvement. A relative approach allows CMS to assess performance within the context of national variation among eligible kidney transplant hospitals and evolving clinical outcomes, rather than relying on fixed thresholds that may not reflect ongoing advancements in transplant care.

At the same time, we recognize the importance of ensuring that performance assessment remains both fair and meaningful. As discussed in comment responses noted previously in this section, we will be finalizing an updated composite graft survival rate scoring methodology, as outlined in Table 8, to reduce sharp performance differentials between thresholds and to more effectively balance performance differentiation with stability. We believe these modifications help mitigate concerns regarding penalizing IOTA participants whose outcomes meet acceptable clinical standards, while simultaneously maintaining appropriate incentives for improvement. However, we will take these comments into consideration as we continue to evaluate the quality domain methodology and may consider alternative approaches, including the potential role of absolute benchmarks, in future notice and comment rulemaking.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing our proposed scoring methodology for performance on the composite graft survival rate in the quality domain, with modification. In response to public comments we received we are modifying the methodology for the allocation of points. Specifically, we are finalizing, with modification Table 1 to paragraph (d) at § 512.428 to reflect the updated points allocation, as illustrated in Table 8. We intend to analyze and monitor IOTA participant performance through the model test to ensure we do not unduly disadvantage kidney transplant hospitals selected for the model. If analysis results indicate that a change in policy is warranted, we will address it pursuant to future notice and comment rulemaking.

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 96280), 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 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 in the 2024 Final Rule (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.

In the 2025 Proposed Rule we stated that 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 (90 FR 57611). 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. In the 2025 Proposed Rule, CMS solicited 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 sought comment on whether CMS should include MA transplants in the calculation for upside risk payments and downside risk payments. We also sought 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.

In the 2025 Proposed Rule (90 FR 57611), we stated that 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 was 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. In the 2025 Proposed Rule, we stated that under this approach, CMS could potentially 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. We explained that 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 sought 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.

As discussed in the 2025 Proposed Rule (90 FR 57611), 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 sought 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.

In accordance with 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 (90 FR 57611). At the same time, CMS is interested in opportunities to achieve greater alignment between MA and Medicare FFS payment methodologies.

Given the factors described in this section, CMS solicited comments from a broad range of stakeholders and interested parties, including MA plans, beneficiary advocates, healthcare providers, and industry experts. We were particularly interested in comments on how MA could play a role in the IOTA Model. Specifically, we invited 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 extended our sincerest appreciation in advance to all commenters, as their valuable feedback will serve to inform future CMS policy actions in this domain.

The following is a summary of the public comments received on the alternative payment design we considered in the 2025 Proposed Rule (90 FR 57611), as described in this section, and our responses:

Comment: Multiple commenters observed that rates of MA enrollment among the Medicare population with ESRD are increasing and that, absent any policy modifications by CMS, the incentives associated with the model would diminish over the course of the IOTA Model performance period. In particular, some of these commenters noted that the rate of ESRD enrollment in MA is projected to reach 60 percent by 2030, according to the latest projections from the CMS Office of the Actuary.

Response: We appreciate this feedback from the commenters. 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 was about 45 percent in 2024 and is projected to drop to approximately 40 percent by 2029.[56] This projected decline in relative enrollment in Medicare FFS between 2024 and 2029 would likely reduce the overall incentive payments under the model by more than 10 percent over those years, without any further action taken by CMS, which could affect the incentive effects of the model test. Additionally, we also recognize that the distribution of beneficiaries enrolled in MA is not uniform and certain areas with higher current MA penetration or growth in MA enrollment would have less of a potential incentive from the model than those in areas with lower MA enrollment relative to Medicare FFS as a higher percentage of the transplants performed by an IOTA participant would be for patients with MA, rather than Medicare FFS, decreasing the magnitude of their upside or downside risk payments.

In consideration of the comments received and as discussed in more detail later in this section, we are finalizing adoption of the alternative payment design described in the 2025 Proposed Rule, in part, to provide for upside and downside risk payments to IOTA participants based on the total number of transplants made to attributed patients with any Medicare primary or secondary coverage, including both Medicare FFS and MA. Specifically, we are finalizing an

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56 Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2027 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* (Apr. 6, 2026), at 27, https://www.cms.gov/files/document/2027-announcement.pdf

update to the definition of Medicare kidney transplant at § 512.402 to mean a kidney transplant furnished to an attributed patient in the IOTA Model whose primary or secondary insurance is Medicare FFS or MA, as identified in Medicare FFS claims with MS-DRGs 008, 019, 650, 651, and 652[57], or through OPTN data.

Comment: Several commenters expressed support for the inclusion of MA beneficiaries in the calculation for the upside risk payment and downside risk payment as IOTA participants are already reimbursed for costs for their MA patients directly from Medicare FFS organ acquisition costs. A commenter also noted that Medicare cost reports do not differentiate between Medicare FFS beneficiaries and MA beneficiaries. The commenter recommended that the IOTA Model follow suit in its calculation of the upside risk payment and downside risk payments.

Response: We thank the commenters for their support and feedback. Accounting for kidney transplants performed for patients with MA in the IOTA payment calculations aligns with the precedent already set in this area where transplant hospitals receive payments for organ acquisition costs directly from Medicare FFS, even for patients with MA.

Comment: Multiple commenters urged CMS to include MA beneficiaries in the calculation of the upside risk payment and downside risk payment to help align payment policies across payers.

Response: We thank commenters for their support and agree on the importance of multi-payer alignment. We believe updating the calculation of the upside risk payment and downside risk payment to account for MA enrollees will help avoid any potential incentives for IOTA participants to target kidney transplants to attributed patients with Medicare FFS over attributed patients with MA.

Comment: Several commenters indicated that, while they endorsed the inclusion of MA

57 See Table 12 in the 2024 Final Rule (89 FR 96381) for a full description of MS-DRGs 008, 019, 650, 651 and 652.

beneficiaries in the calculation of the upside risk payment and downside risk payment, they were unable to support this alternative consideration if the maximum upside risk payment were simultaneously reduced from $15,000 to $10,000, as described in section II.B.3.b. of the 2025 Proposed Rule.

Response: We thank the commenters for their feedback. In response to the comments we received and additional analyses from the CMS Office of the Actuary suggesting that this would not have a large effect on projected model savings, we will be finalizing this alternative consideration with modification. Specifically, we are finalizing as considered in section II.B.3.b. of the 2025 Proposed Rule the modification to the definition of Medicare kidney transplant at § 512.402 and our regulatory text at § 512.470 to provide a waiver of section 1851(i)(2) of the Act and 42 CFR 422.322(c) to allow for the inclusion of kidney transplants furnished to attributed patients enrolled in MA in the definition of Medicare kidney transplants 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. However, rather than lowering to the maximum upside risk payment allotment per Medicare kidney transplant to $10,000, as considered in section II.B.3.b. of the 2025 Proposed Rule, the maximum upside risk payment per Medicare kidney transplant will remain at $15,000.

Comment: Several commenters expressed concern that including MA beneficiaries in the calculation of upside and downside risk payments would increase administrative burden. Commenters specifically cited concerns regarding additional data costs associated with integrating data across payers, as well as potential additional notification requirements.

Response: We thank the commenters for their feedback. We note that the inclusion of MA beneficiaries in the calculation of the upside risk payment and downside risk payment affects only the relative magnitude of upside and downside risk payments for IOTA participants and does not change existing accountability for total kidney transplant volume, which applies regardless of payer under the achievement domain. As such, we do not anticipate that finalizing

this provision will introduce additional operational burden or new data analysis requirements for IOTA participants. We also note that the notification requirements under the IOTA Model apply to all Medicare beneficiaries, regardless of whether they are enrolled in Medicare FFS or MA, and, therefore, do not represent a new or incremental requirement associated with this policy.

Comment: Multiple commenters raised concerns regarding the differences in incentives between the IOTA Model and the COE requirements from different MA plans and raised concerns about their ability to succeed on both sets of metrics. A commenter raised concerns that the outcomes metric used for the Quality Domain in the IOTA Model, especially given that it is not risk adjusted for PY 1, does not align with the methodology used by most plans for their COE designations and that use of more complex organs could cause them to lose COE status.

Response: We thank the commenters for their comments regarding the potential impact of incorporating MA kidney transplants into the calculation of upside and downside risk payments on their ability to meet COE requirements across different plans. A kidney transplant hospital receives COE designation from a private insurer when it meets transplant volume and performance thresholds. Without this designation, a kidney transplant hospital may not be approved by certain private insurance companies to complete a kidney transplant procedure, which limits the kidney transplant hospitals where patients may receive covered care. However, as described in comment responses noted previously in this section, updating the calculation of the upside risk payment and downside risk payment to account for transplants furnished to MA enrollees would only affect the relative magnitude of upside risk payments or downside risk payments for IOTA participants. The IOTA Model is designed to test the concept of holding IOTA participants accountable to a comprehensive set of metrics focused on achieving a certain threshold of kidney transplants, organ offer acceptance rates, and post-transplant outcomes. These metrics are comparable to COE requirements that we have identified, such as this sample one linked here,[58] which require a minimum volume threshold and performance above the

58 Aetna. (2024, January 1). Aetna Institutes of Excellence® transplant facilities: Summary of criteria.

minimum SRTR thresholds for 90-day and 1-year graft survival rates. We believe that IOTA participants' quality improvement activities implemented as a result of the model's performance metrics and payment methodology may help them reach and maintain COE status.

Though there are similarities between insurer COE requirements and IOTA metrics, CMS recognizes that existing COE requirements from MAOs and private insurers are generally focused on achieving a minimum volume standard to ensure that a center is proficient at performing transplants, rather than on increasing kidney transplant volume as emphasized in the IOTA Model. CMS acknowledges that this distinction may be attributable, in part, to factors that make it difficult for MAOs to capture potential savings that accrue when a transplant occurs. Associated savings from additional transplants are realized when a beneficiary transitions from a higher-cost eligibility category (as an ESRD beneficiary) to a lower-cost category (as a post-transplant beneficiary). MAOs may not directly benefit from these transitions, given the fact that MAOs receive capitated payments based on beneficiary category, the fact that savings associated with transplantation materialize over multiple years due to the substantial upfront costs of organ acquisition, transplantation, and recovery, and the uncertainty of continued beneficiary enrollment over time. These factors reduce the likelihood that MA plans may independently implement incentive mechanisms comparable to those established under the IOTA Model.

Comment: Multiple commenters raised concerns that the inclusion of MA beneficiaries in the calculation of upside and downside risk payments could potentially constitute a violation of the non-interference clause in section 1854(a)(6)(B)(iii) of the Act, which provides that the Secretary may not require any MAO to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract.

Response: We thank the commenters for their feedback; however, we respectfully

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https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/Aetna-Institutes-of-Excellence.pdf

disagree that including MA beneficiaries in the calculation of upside and downside risk payments under the IOTA Model implicates the non-interference clause. Under this policy, MA plans retain full authority to negotiate payment arrangements with contracted providers without interference from the model. The non-interference clause prohibits CMS from interfering in negotiations between MA plans and their contracted providers to require MAOs to contract with a particular provider or require a particular price structure for payment. The inclusion of kidney transplants furnished to MA enrollees in the calculation of upside and downside risk payments does not regulate, direct, or otherwise influence those negotiations, nor does it impose requirements on MA plans. Rather, it applies solely to IOTA participants by incorporating transplant activity across payers into model-based payment calculations. MA plans retain full discretion to negotiate contracts and establish reimbursement rates with network providers without interference from the model. We also note that the IOTA Model operates independently of plan-provider contracting cycles. MA plans typically negotiate contracts with transplant hospitals prior to the start of a calendar year, whereas IOTA Model PYs conclude 18 months after the start of the respective calendar year, and payment adjustments are calculated retrospectively. For example, an IOTA participant's rates for PY 1, which began on July 1, 2025, would have been negotiated before the end of 2024, but the IOTA Model will not finish its calculations until after the PY ends on June 30, 2026. For these reasons, we do not believe that including MA beneficiaries in the calculation of upside and downside risk payments would have an impact on contract negotiations between MA plans and providers.

Comment: A commenter recommended that the alternative consideration regarding the inclusion of kidney transplants furnished to attributed patients enrolled in MA within the definition of Medicare kidney transplants—such that upside risk payments and downside risk payments would be based on kidney transplants for beneficiaries with Medicare FFS or MA as a primary or secondary payer—be implemented on a voluntary basis, and further urged that CMS update the model accordingly to reflect voluntary participation.

Response: As described in the 2024 Final Rule (89 FR 96304), a mandatory model is necessary to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care. A mandatory model would also minimize the potential for selection bias, thereby ensuring that the model participants are a representative sample of kidney transplant hospitals. We believe a mandatory model is necessary to obtain relevant information about the effects of the model's policies on kidney transplant hospital behavior.

Comment: A commenter suggested that implementation of this provision would be premature, citing uncertainty regarding its potential implications for MA Star Ratings and risk-adjustment if it were finalized.

Response: CMS does not believe that adjusting the magnitude of payments for IOTA Model participants to account for MA enrollees would have any operational impact on MAOs. All payments under the IOTA Model occur directly between CMS and the IOTA participants. Additionally, Star Ratings should not be affected by a change in payment amount received by IOTA participants, given that the MAO would not have a role in this area. Furthermore, the CMS Office of the Actuary does not project that this would impact rates or risk adjustment for MAOs. Their analyses project an additional 4,766 transplants over the six-year period of the model, which is dwarfed by the tens of millions of beneficiaries enrolled in the Medicare program.

Comment: Multiple commenters raised concerns about certain actions taken by MAOs, including prior authorization requirements and limited contracted networks of transplant hospitals, noting that these policies may constrain patients' ability to receive a transplant. Commenters requested additional data regarding the effects of these various policies implemented by MAOs.

Response: We thank the commenters for their feedback regarding the potential impact of MA utilization management policies and limited networks of kidney transplant hospitals on

transplant access. We note that including MA enrollees in the calculation of the upside risk payment and downside risk payment affects only the relative magnitude of upside and downside risk payments for IOTA participants and does not alter the achievement domain, in which IOTA participants are already held accountable for total kidney transplant volume regardless of payer. We also recognize the rapid growth in MA enrollment among patients with ESRD following implementation of the 21st Century Cures Act. As part of the model evaluation for the IOTA Model, we intend to examine effects of the model by payer, and where feasible, investigate the role of MA utilization management policies and networks on results for patients. We believe it is important to know the differential effects of the model by payer and the ability of different kidney transplant hospitals to navigate utilization management requirements.

Comment: We received comments supporting the proposed reduction in spending for the maximum upside risk payment. Commenters pointed out that it was a reasonable policy tradeoff that could ensure budget neutrality and could leave total IOTA participant upside payments at a relatively similar amount relative to the standards for PY 1.

Response: We appreciate the feedback from commenters. CMS' intent in proposing this provision was to achieve that tradeoff and to ensure that total model savings exceeded model payments. We are planning to update our approach as described below and in recognition of the dynamic effects of increased payment amounts. Our final decision to leave the upside risk payment at $15,000 came after updated analyses from the CMS Office of the Actuary that showed an increased incentive effect from higher payments that could ensure more beneficiaries receive kidney transplants and additional savings for the Medicare Trust Fund.

Comment: Multiple commenters expressed support for the alternative consideration that would reduce the maximum upside risk payment, as well as for the inclusion of kidney transplants furnished to attributed patients enrolled in MA within the definition of Medicare kidney transplants.

Response: We thank the commenters for their support. As mentioned in comment

responses noted previously in this section, we will not be finalizing the alternative consideration that would reduce the maximum upside risk payment due to updated calculations from the CMS Office of the Actuary and comments from stakeholders that demonstrate that maintaining the payment at $15,000 has a positive incentive effect on encouraging more kidney transplants. We direct readers to section IV. of this final rule for a full discussion on how keeping the maximum upside risk payment at $15,000 is projected to provide a larger incentive for IOTA participants to improve performance in the model. However, as described in comment responses noted previously in this section, we will be finalizing the inclusion of kidney transplants furnished to attributed patients enrolled in MA within the definition of Medicare kidney transplants.

Comment: Multiple commenters expressed disagreement with the alternative consideration that would reduce the maximum upside risk payment, noting that higher incentive payments are necessary to support the requisite investments in technology and care coordination essential for success within the model. Several of these commenters further observed that more complex organs can frequently result in higher costs associated with kidney transplantation due to delayed graft function.

Response: We appreciate this feedback from commenters and are not finalizing the reduction in payments laid out in the 2025 Proposed Rule.

Comment: Commenters noted that the updated savings estimates in the 2025 Proposed Rule show a higher savings for the Medicare Trust Fund that occurs when a patient with MA receives a kidney transplant, as opposed to a patient with Medicare FFS.

Response: We agree with commenters on this issue. In the 2025 Proposed Rule, the CMS Office of the Actuary projected that federal savings would be approximately $5,000 greater for the average additional kidney transplant under MA because risk scores tend to over-project ESRD spending for beneficiaries meeting the clinical criteria for transplantation (90 FR 57628). The CMS Office of the Actuary performed an analysis that showed that 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, while post-transplant spending is similar. Assuming 45 percent of new kidney 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 do not currently include kidney transplants for beneficiaries with MA in calculating model payment incentives. This is also in part why, in this final rule, CMS is updating the regulations to account for MA beneficiaries who receive a kidney transplant in upside and downside risk payments.

Comment: Multiple commenters expressed concern regarding the incentive effects arising from the alternative consideration that would reduce the maximum upside risk payment multiplier from $15,000 to $10,000 per Medicare kidney transplant. In particular, a commenter expressed concern that reducing the maximum upside risk payment multiplier to $10,000 would weaken the incentives in the model that support meaningful expansion of transplant capacity. The commenter stated that expanding transplant access requires sustained investment in specialized personnel, patient navigation, care coordination, data analytics, and post-transplant monitoring. The commenter cited evidence from other alternative payment models suggesting that incentives must be of sufficient magnitude and predictability to effectuate provider behavior change, particularly in circumstances where participation is mandatory.

The commenter noted that feedback from transplant programs indicates that the reduction, when considered in conjunction with increasing administrative and transparency requirements, may not adequately offset the costs associated with investing in center capacity and utilization of more complex organs that require longer hospital stays. The commenter further stated that in a labor-constrained environment, insufficient upside potential may serve as

a disincentive to the investments that are central to achieving the model's access goals. The commenter urged CMS to retain the current maximum upside risk payment multiplier of $15,000 per Medicare kidney transplant or, in the alternative, to provide transparent empirical analysis demonstrating that the reduction to $10,000 remains sufficient to sustain participation and investment across diverse transplant programs.

Response: We agree with commenters on this response. Our updated analysis from the CMS Office of the Actuary shows that keeping the maximum upside risk payment multiplier at $15,000 is projected to provide a larger incentive for IOTA participants to better perform in the model. We direct readers to section IV. of this final rule for a full discussion on how keeping the maximum upside risk payment at $15,000 is projected to provide a larger incentive for IOTA participants to better perform in the model.

After consideration of public comments received, for the reasons set forth in this rule, we are finalizing our alternative consideration to calculate upside and downside risk payments to the IOTA participants based on the total number of kidney transplants made to attributed patients with any Medicare primary or secondary coverage, including both Medicare FFS and MA, for the IOTA Model with modification. We are revising the definition of Medicare kidney transplant definition at § 512.402 to include transplants furnished to attributed patients with MA, to further the incentive effects of the IOTA Model and to recognize the growing trend in MA enrollment. Specifically, we are revising the definition of Medicare kidney transplant at § 512.402 to mean a kidney transplant furnished to an attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS) or MA, as identified in Medicare FFS claims with MS-DRGs 008, 019, 650, 651, and 652, or through aggregate OPTN data that would be able to identify transplants for patients with MA.

We are also revising the regulatory text at § 512.470 to provide a waiver of section 1851(i)(2) of the Act and 42 CFR 422.322(c) to allow for the inclusion of transplants furnished to attributed patients enrolled in MA in the definition of Medicare kidney transplants 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. Specifically, at § 512.470 we are removing the phrase "and 1833(b) of the Act" and adding in its place the phrase "1833(b), and 1851(i)(2) of the Act, and 42 CFR 422.322(c)". We do recognize that this waiver has not been used before by CMS. To ensure that there are not unintended negative consequences, CMS will plan to evaluate the effect of this policy on IOTA participants and see if there is any impact on the number of kidney transplants delivered to patients with MA compared to Medicare FFS. This analysis would look at effects of the model between the different payers and also look at any particular regional effects from the model. This will be shared publicly as part of CMS' evaluation of the IOTA Model. Additionally, CMS will track incentive payments made for patients with MA and Medicare FFS separately and assess their effects. Finally, CMS is interested in seeing any effect on MA plan negotiated rates with IOTA participants before and after implementation of this policy and seeks feedback from the public, MAOs, and IOTA participants about how to best track this information.

Additionally, in response to the comments we received, we will maintain the maximum upside risk payment multiplier per Medicare kidney transplant at $15,000, rather than lowering the maximum upside risk payment multiplier per Medicare kidney transplant to $10,000, as considered in section II.B.3.b. of the 2025 Proposed Rule. We believe that this will help to ensure the strongest incentive for IOTA participants to better perform in the IOTA Model, while still ensuring overall savings for the model.

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 9. Additionally, we finalized the definitions of downside risk payment, upside risk payment, and neutral zone at § 512.402.

TABLE 9: 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

As discussed in the 2025 Proposed Rule (90 FR 57612), we previously finalized our policy that for PYs 2 through 6 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 9. Since publication some IOTA participants have expressed confusion about final performance scores of 40 points and 60 points. In the 2025 Proposed Rule (90 FR 57612), we proposed 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 9, 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 proposed 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 proposed 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 (90 FR 57612). Additionally, we proposed 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 proposed at § 512.430(b)(3) to clarify that if an IOTA participant's final performance score is below 40 points in PYs 2 through 6, the IOTA participant qualifies for a downside risk payment.

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

The following is a summary of the comments received on our proposals at proposed § 512.430(b)(1), (b)(2)(ii), and (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 and our responses:

Comment: A few commenters expressed support for the clarification of 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.

Response: We thank the commenters for their support.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposals to clarify the appropriate final performance score ranges for an IOTA participant to be eligible to receive an upside risk payment, be in the neutral zone, or receive a downside risk payment at § 512.430(b)(1), (b)(2)(ii), and (b)(3)(i) without modification, as illustrated in Table 10.

TABLE 10: UPDATED PERFORMANCE-BASED PAYMENTS BY FINAL PERFORMANCE SCORE

Final Performance Score	PY 1	PY 2 – 6
61-100	Upside Risk Payment	Upside Risk Payment
40-60 (Inclusive)	Neutral Zone	Neutral Zone
0 - 39	Neutral Zone	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 proposed 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 (90 FR 57612). 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, in accordance with 31 U.S.C. 3711(g).

We sought 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.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters suggested extending the proposed 60-day timeline for remitting downside risk payments, with suggestions including a timeline similar to the deadline for CMS to make bonus payments, no payment being due while there is an existing appeal of a penalty determination, and leniency for smaller providers to allow installment payments.

Response: We appreciate the commenters' concerns regarding the 60-day timeline for remitting downside risk payments. The original rule contained a typographical error wherein CMS will invoke all legal means to collect the debt if the payment has not been made within 60 days, rather than at least 60 days, after the date on which demand is issued. This timeframe is consistent with other CMS debt collection practices. Additionally, there are existing mechanisms in place for an IOTA participant to contest any monies owed. Therefore, we are finalizing this policy as proposed. In addition, the requested leniency for smaller providers was not included in the 2025 Proposed Rule; and therefore, we are not finalizing the revisions suggested by the commenter in this final rule.

Comment: A commenter expressed support for the proposals to finalize the downside risk payment.

Response: We thank the commenter for their support.

After consideration of the public comments we received, for the reasons set forth in this

rule, we are finalizing our proposed provisions for clarifying that full payment of a downside risk payment must be received within 60 days after the demand is made and if the IOTA participant fails to repay CMS in full within that timeframe, CMS will invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of Treasury, at § 512.430(d)(6)(ii) without modification.

(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.

As stated in the 2025 Proposed Rule (90 FR 57612), 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 or more of the measures were disrupted by an EUC event.

Therefore, we proposed 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 (90 FR 57612 through 57613). Additionally, we proposed 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 proposed 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 sought 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 sought 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.

The following is a summary of the comments received on our proposal 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, as well as the flexibilities at proposed § 512.436(b) that CMS may adjust upside or downside risk payments to respond to a potential emergency faced by an IOTA participant and our responses:

Comment: Multiple commenters expressed support for increased flexibility for

acknowledging extreme and uncontrollable circumstances and the ability for CMS to account for the effects of disasters when measuring performance in the IOTA Model for IOTA participants. Commenters supported CMS extending its purview beyond forgiving a portion of shared losses when considering the effects of an EUC situation.

Response: We appreciate the feedback and believe that this flexibility will be useful in responding to circumstances outside of the control of model participants. This will enable CMS to potentially account for numerous situations that could occur during an EUC situation, including a scenario where the EUC situation causes an IOTA participant to perform fewer than the required minimum number of kidney transplants during a performance year.

Comment: Multiple commenters expressed concerns about using the Stafford Act definition for when an EUC occurs. Commenters were concerned about a governor being required to declare the disaster and urged CMS to remain with the standard set up by the Quality Payment Program.

Response: We appreciate this feedback from commenters and recognize the potential concerns that could occur. As a result, we believe it would be superior to continue using the standard established by the QPP to determine when an EUC occurs, given that it is an internal CMS standard, rather than a definition that depends on outside sources.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing the proposed changes to § 512.436 (a)(1) in order to continue relying on the internal CMS standard of the Quality Payment Program for designating when an Extreme and Uncontrollable circumstance has occurred and the affected area during the PY. However, we are finalizing without modification the provisions as proposed at § 512.436 (b), which grants CMS increased flexibility to respond to EUC scenarios.

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).

As stated in the 2025 Proposed Rule, to advance transparency for individuals seeking transplant waitlist access and to improve patient health literacy regarding transplant program evaluation processes, we proposed to revise § 512.442(a) (90 FR 57613). Specifically, we proposed 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 (a)(1). For all subsequent PYs, we proposed 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. We stated in the 2025 Proposed Rule that 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 the 2025 Proposed Rule (90 FR 57613), we stated that in recognition that transplant hospitals may make changes to the 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 believed this policy would address commenters' suggestions and provide flexibility in updating its waitlist selection criteria on its website. We sought comment on these proposals at proposed § 512.442(a)(1) and (2).

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 (90 FR 57613). We recognized 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 final rule, in the IOTA Model. We sought public comment on the alternatives considered.

As stated in the 2025 Proposed Rule, 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 (90 FR 57613). 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 recognized 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 proposed 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 proposed 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 believed 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 (90 FR 57613). Additionally, we believed 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 sought comment on these proposals at proposed § 512.442(a)(3)(i) and (ii). Finally, we proposed 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 (90 FR 57613). We recognized 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 final rule, in the IOTA Model. We sought 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 (90 FR 57614). 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 did not propose to provide standardized waitlist selection criteria or living donor selection criteria templates that IOTA participants would be required to use, we sought 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 sought comment on what specific requirements or specific detail should be included in standardized waitlist selection criteria or living donor selection criteria templates.

The following is a summary of the public comments received on all of the publication of selection criteria proposals and alternatives considered set out in this section and our responses:

Comment: Several commenters expressed their general support for requiring IOTA participants to review and publicly post the criteria used for evaluating and selecting patients for addition to their kidney transplant waitlist. A commenter supported the proposal, noting that the information is already available and that the absence of a mandate for standardized templates allows IOTA participants to determine the most appropriate information to discuss with their community. Another commenter observed that the publication of selection criteria enhances transparency by affording patients the opportunity to make informed decisions while maintaining consistent reporting requirements across IOTA participants. An additional commenter stated that this initiative serves to empower patients, as they may not otherwise be aware of the criteria employed at different kidney transplant hospitals.

Response: We thank the commenters for their support of the requirement that IOTA participants review and maintain up to date criteria used to evaluate and select patients for addition to their kidney transplant waitlist. We agree that ensuring this information is publicly available and periodically reviewed promotes transparency and helps patients better understand

transplant program evaluation processes. We also agree with commenters that making these criteria publicly accessible can help patients and referring clinicians better anticipate evaluation requirements across transplant hospitals and support more informed decision making prior to transplant evaluation. By encouraging transparency early in the transplant journey, we believe this policy may empower patients and contribute to a more efficient and informed transplant evaluation process. For these reasons, we are finalizing this proposal without modification.

Comment: Several commenters expressed support for requiring IOTA participants to review their publicly posted criteria used for evaluating and selecting patients for addition to the kidney transplant waitlist for each subsequent performance year. A few of these commenters noted that the requirement aligns with existing practices and would not create significant additional administrative burden.

While supporting the proposal, a commenter suggested including the date of the most recent review in the publicly posted criteria. Another commenter commended the initiative for empowering patients and supporting more informed decision making by patients and their care teams, noting that access to this information may help patients select the most appropriate transplant hospital, particularly when insurance limits the number of transplant evaluations permitted each year. This commenter also recommended that CMS and HRSA collect and publish additional data on pre-waitlisting processes, including the number of referred patients and the number who begin and complete transplant evaluations.

Additionally, a commenter stated that the proposal appropriately balances improving patient understanding with recognizing operational burden. The commenter further recommended that CMS complement transparency efforts by collecting and publishing anonymized, summary-level data regarding reasons transplant hospitals decline organ offers and the eventual disposition of those organs to improve public understanding of transplant decision making and identify potential inefficiencies in the organ allocation system.

Response: We thank the commenters for their support of the proposal requiring IOTA

participants to review their publicly posted criteria used for evaluating and selecting patients for addition to the kidney transplant waitlist for each subsequent performance year. We agree that this requirement aligns with existing practices for many IOTA participants and should not impose significant additional administrative burden. As described in this section of this final rule, § 512.442(a)(2) requires IOTA participants to review and ensure that their publicly posted waitlist selection criteria remain current by the end of each relevant performance year, which we believe promotes transparency while maintaining operational flexibility.

As mentioned in comment responses noted previously in this section, we are finalizing this provision without modification. However, we appreciate the suggestion to include the date of the most recent review within the publicly posted criteria and the broader recommendations to expand transparency through additional data collection, such as information on pre-waitlisting referrals, evaluation completion rates, or reasons transplant hospitals decline organ offers. We also acknowledge commenters' views that providing clear information about transplant evaluation criteria can empower patients and their care teams to make informed decisions when selecting transplant hospitals, particularly when insurance coverage limits the number of evaluations permitted each year. While the provision focuses on ensuring the accuracy and transparency of IOTA participant selection criteria, we recognize the potential value of additional data transparency initiatives and may consider such suggestions in coordination with HRSA and other stakeholders in future policy development or notice and comment rulemaking.

Comment: A commenter expressed general support for the proposal requiring IOTA participants to review and maintain up to date their publicly posted criteria used to evaluate and select patients for addition to the kidney transplant waitlist each performance year, indicating they understood and supported the intent of this annual requirement as a means of promoting transparency in kidney transplant evaluation processes.

Response: We thank the commenter for their support.

Comment: A commenter expressed support for the requirement that IOTA participants

publicly post the criteria used to evaluate and select patients for addition to their kidney transplant waitlist. The commenter also recommended that CMS consider auditing this practice to ensure compliance and consistency. In addition, the commenter suggested that CMS define what constitutes selection criteria and provide examples of key areas that should be addressed in the publicly posted criteria.

Response: We appreciate the commenter's support. We acknowledge that we inadvertently omitted transparency requirements in the inclusion of monitoring activities for PY 1. However, as described and finalized in section II.B.6 of this final rule, we are finalizing our proposed provisions for monitoring the transparency requirements at § 512.462(b)(2)(xi), (xii), and (xiii) with modification. We direct the commenter to section II.B.6. of this final rule for further discussion on monitoring activities for transparency requirements included in the IOTA Model.

We acknowledge that certain IOTA participants may maintain distinct criteria for the initial consideration and evaluation of a kidney transplant waitlist patient as compared to the criteria for selection and addition to the waitlist, while other IOTA participants may regard evaluation and selection as encompassing a unified set of criteria. We would also like to clarify that the intent of requiring the publication of selection criteria provision is to promote transparency regarding the requirements that patients must realistically fulfill, both prior to and following evaluation, in order to successfully advance to addition on the waitlist.

As mentioned in comment responses noted previously in this section, we are finalizing this provision without modification. While we will not require IOTA participants to use selection criteria templates for the posting of this information on its websites, we encourage IOTA participants to consider incorporating categories such as potential disqualifications, absolute and relative contraindications to kidney transplant, or, alternatively, factors that may delay or promote readiness for kidney transplant. For example, such criteria could potentially include, but not be limited to, guidance pertaining to body mass index, smoking status, active

substance use, psychosocial requirements, cardiac and pulmonary function, physical functioning status, active demonstration of adherence to appointments and medications, state of vascular disease, ability for temporary relocation for post-transplant follow-up, active cancers, life expectancy, and active insurance coverage for surgical procedures and lifelong transplant medications. We acknowledge that many patients may receive resources during their transplant evaluation, such as guidance to achieve weight loss or to develop a financial plan or social support system, in order to meet qualification requirements. Accordingly, the specificity and explanations of selection criteria remain at the discretion of the IOTA participant to address the needs of their local populations and kidney transplant hospital. We also encourage IOTA participants to present their selection criteria in a manner that is comprehensible to patients of varying education levels and in an accessible format.

Comment: Several commenters recommended that CMS establish a centralized dashboard to publish the criteria used by IOTA participants for evaluating and selecting patients for addition to their kidney transplant waitlist, rather than requiring individual IOTA participant websites to host such information, thereby enhancing accessibility and reducing administrative burden. Additionally, it was suggested that the criteria should be presented as a means of patient preparation rather than discouragement, and that this centralized platform should be developed over time to serve as a comprehensive repository for patient resources.

Response: We appreciate the commenters' recommendation to establish a centralized location for the posting of selection criteria. As described and finalized in section II.B.4.a(2) of this final rule, CMS will publish IOTA participant waitlist selection criteria and living donor selection criteria on the IOTA Model website by the end of the second quarter of each subsequent PY, thereby supplementing the existing requirement for IOTA participants to post such information on their respective websites. While this is not a dashboard, this centralized approach is intended to enhance accessibility and transparency for patients and other stakeholders. We direct readers to section II.B.4.a(2) of this final rule for a full discussion of

these policies.

We also agree that the manner in which selection criteria are presented is of considerable importance to patient engagement. IOTA participants are encouraged to frame such information in a manner that supports patient preparation and comprehension, including the emphasis of modifiable factors that may assist patients in preparing for kidney transplant evaluation, rather than presenting criteria in a manner that may be perceived as discouraging.

Comment: A commenter expressed support for CMS's proposal requiring IOTA participants, for each subsequent PY, to review and maintain up to date the publicly posted criteria used for evaluating and selecting patients for addition to the kidney transplant waitlist by the end of each relevant PY, noting that this provision promotes transparency. The commenter also suggested that selection criteria include information on therapies or options available for highly sensitized patients to further support patient empowerment and informed decision making.

Response: We thank the commenter for their support and recommendation. We recognize the importance of providing information that may support patient understanding and empowerment, including considerations relevant to highly sensitized patients. However, as described in comment responses noted previously in this section, we are not prescribing specific content requirements for how criteria used by IOTA participants for evaluating and selecting patients for addition to their kidney transplant waitlist must be presented.

IOTA participants retain flexibility in determining how to present their selection criteria and related information to best meet the needs of their patient populations. This may include, at the discretion of the IOTA participant, information on factors such as high PRA considerations and potential options to expand transplant opportunities, including paired kidney exchange programs or desensitization therapies.

Comment: A few commenters recommended that CMS modify the frequency of the proposed provision requiring IOTA participants to review their publicly posted criteria used to evaluate and select patients for addition to the kidney transplant waitlist, as well as living donor

selection criteria for IOTA participants performing living donor kidney transplants, from an annual review to once every three years. The commenters indicated that aligning the review frequency with the 3-year accreditation cycle for transplant hospitals would more accurately reflect existing operational practices and reduce administrative burden.

Response: We thank the commenters for their recommendation to align the review of selection criteria with the three-year accreditation cycle; however, we do not agree that extending the review frequency to every three years is appropriate. Transplant hospitals operate on different accreditation timelines, which could result in significant variation in how current publicly posted criteria are across IOTA participants. Over a three-year period, regulatory requirements, clinical practices, and transplant program policies may change, and less frequent updates could result in outdated information being presented to patients and referring clinicians.

We also note that variability in update timing could create inconsistencies for patients comparing IOTA participants, particularly if some of them have more recently updated criteria while others have not. We believe that requiring annual review and updating of selection criteria better supports transparency, accuracy, and equitable access to information, especially given the dynamic nature of transplant practices and the continuous flow of patients entering and progressing through the transplant process. For these reasons, and those described in this section, we are finalizing the frequency of these provisions without modification.

Comment: Several commenters expressed support for the proposal requiring IOTA participants that perform living donor kidney transplants to publicly post their living donor selection criteria on their websites. Commenters stated that this initiative would improve transparency, support informed decision making for kidney transplant waitlist patients, and promote greater consistency across transplant hospitals.

Commenters also noted that the information is generally already available and that the absence of a mandated template allows IOTA participants flexibility to tailor how criteria are presented to best meet the needs of their communities. Additionally, commenters indicated that

the proposal appropriately balances enhancing patient understanding with minimizing administrative burden and is not expected to impose significant additional workload on IOTA participants.

Response: We appreciate the commenters' support for the proposal requiring an IOTA participant that performs living donor kidney transplants to publicly post its living donor selection criteria on its website. We agree that making these criteria publicly available enhances transparency, supports informed decision-making for kidney transplant waitlist patients and their families, and promotes greater consistency across transplant hospitals. We believe that providing access to living donor selection criteria enables patients, potential donors, and referring clinicians to more thoroughly understand evaluation requirements and adequately prepare for the living donation process.

We further agree with commenters that this requirement is unlikely to impose significant additional administrative burden, as many IOTA participants already maintain such information and the policy does not prescribe the use of a standardized template. This flexibility permits IOTA participants to tailor the manner in which criteria are presented to best serve the needs of their respective communities while ensuring that essential information remains accessible. By achieving an appropriate balance between transparency and operational flexibility, we believe this provision supports patient understanding and engagement without imposing undue burden. For these reasons, we are finalizing § 512.442(a)(3) without modification.

Comment: A few commenters expressed support for requiring IOTA participants that perform living donor kidney transplants to publicly post their living donor selection criteria, including the requirement to review and update this information for each subsequent PY. A commenter suggested that CMS also require inclusion of the date of the most recent review to enhance transparency and clarity for patients and stakeholders.

Another commenter commended the initiative for empowering patients, noting that access to this information may support more informed decision making and improve efficiency

for patients and their care teams. Additionally, a commenter agreed with the requirement, stating that clearly defined threshold criteria may help potential living donors better prepare for evaluation, and recommended that CMS clarify which stage of the evaluation process the posted selection criteria are intended to address.

Response: We thank the commenters for their support of the requirement for IOTA participants that perform living donor kidney transplants to publicly post and annually review their living donor selection criteria. In response to the suggestion to include the date of the most recent review, while we did not propose to require this element, we encourage IOTA participants to consider including it to enhance transparency and facilitate tracking for patients, staff, and monitoring purposes.

We also appreciate the request for clarification regarding the stage of the evaluation process addressed by the posted selection criteria. The intent of this provision is to provide potential living donors with a clearer understanding of what to expect during the evaluation process. While we are not mandating specific templates or content, we encourage IOTA participants to present information that may assist with patient preparation, such as potential contraindications or factors that may affect readiness for donation. We note that the level of detail and presentation of this information remains at the discretion of the IOTA participant to best meet the needs of their patient population, and the policy is not intended to discourage potential donors but rather to promote informed understanding and engagement.

Comment: A commenter expressed disagreement with our proposal requiring IOTA participants performing living donor kidney transplants to publicly post their living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients on its websites. The commenter cited concerns regarding administrative burden and redundancy for both CMS and providers, noting that patients already utilize direct sources of information, such as transplant hospital and OPTN websites. The commenter further conveyed concern that transitioning this material to the IOTA Model website could introduce opportunities for errors.

Response: We thank the commenter for their feedback. As mentioned in comment responses noted previously in this section, we are finalizing our provision at § 512.442(a)(3) without modification. As such, IOTA participants that perform living donor kidney transplants will be required to post its publicly posted living donor selection criteria by the end of PY 2 and review and update this information by the end of each subsequent PY thereafter. We note that, if desired, IOTA participants may update this information more frequently. The information posted on IOTA participant websites will serve as the basis for the content published by CMS on the IOTA Model website, as described and finalized in section II.B.4.a(2) of this final rule, which is intended to provide a centralized and accessible source of information for patients and stakeholders. We direct readers to section II.B.4.a(2) of this final rule for further discussion on this provision.

We also acknowledge the availability of resources through the OPTN website. However, it does not currently provide a centralized location for comparing transplant hospital selection criteria. While the IOTA Model website will include only IOTA participants, Innovation Center models are designed to test approaches on a smaller scale with the potential for broader application if successful. CMS does not have the authority to require non-IOTA participants to adopt similar posting practices; however, we encourage all transplant hospitals to consider such transparency efforts to support informed decision-making for living donor candidates.

Comment: A few commenters recommended removing the proposed provision requiring IOTA participants, beginning in PY 3 and for all subsequent PYs, to 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. These commenters cited concerns that such criteria are patient-specific in nature and could either create confusion or deter potential donors, thereby conflicting with the broader objective of increasing access to kidney transplantation

Response: We thank the commenters for their recommendations and acknowledge that

living donor selection involves careful consideration of a multitude of risks and benefits unique to each potential donor. However, given that there is currently no requirement for IOTA participants to post its living donor selection criteria on its website, we believe that establishing baseline criteria will not only encourage more meaningful discussions between kidney transplant waitlist patients and their care teams regarding living donation, but also set reasonable expectations for those patients. We further note that this provision does not include prescriptive specifications requiring IOTA participants to utilize standardized templates. This flexibility affords IOTA participants the discretion to determine the specificity of their criteria, including whether to list absolute or relative contraindications, or to adopt alternative approaches. Given that this provision is not overly prescriptive in nature, we do not believe that it would create confusion or deter prospective living donors.

Comment: A commenter expressed concern that the new publication of living donor selection criteria requirement would impose additional administrative burden without providing clear benefit.

Response: We acknowledge that initial implementation may require IOTA participants to engage in internal discussions to establish and align on living donor selection criteria. However, we do not consider these efforts to be unduly burdensome, but rather necessary to support transparency and patient understanding. Providing this information may help facilitate more efficient evaluations and better prepare potential living donors for the process. We also anticipate that, following initial implementation, subsequent PYs would require only limited updates, as IOTA participants maintain and refine existing living donor selection criteria rather than develop them anew.

Comment: A few commenters expressed support for the use of standardized templates. A commenter specifically supported the development of a uniform, standardized template, preferably created by HRSA or the OPTN, that would encompass absolute contraindications as well as financial, psychosocial, and insurance requirements. Another commenter recommended

that HHS encourage HRSA, through the OPTN Modernization Initiative, to establish a centralized repository incorporating the aforementioned criteria to facilitate comparison among transplant hospitals. This commenter referenced a prior SRTR version as a potential model and suggested that such a tool could be piloted initially by IOTA participants.

Response: We appreciate the commenters' support. We are finalizing these provisions as proposed, but, we will take the commenters' recommendations into consideration for future notice and comment rulemaking. We remain interested in standardized templates as a means to ease the burden on each IOTA participant and to facilitate comparisons across all IOTA participants, provided that such templates can be implemented while maintaining flexibility for IOTA participants and accommodating their independent needs. Furthermore, following the implementation of these requirements, we encourage IOTA participants to engage in ongoing discussions with CMS regarding whether the inclusion of standardized templates would or would not be beneficial.

Comment: Several commenters expressed opposition to the use of standardized templates for publishing waitlist and living donor selection criteria. Some of these commenters stated that standardized templates could limit flexibility for IOTA participants to tailor criteria to their specific kidney transplant hospitals and patient populations. Another commenter raised concerns about potential administrative burden associated with implementing templates. Additionally, a commenter requested further clarification regarding how such a requirement would be implemented. In contrast, another commenter suggested that, if templates were to be developed, they should be created by HRSA or the OPTN to ensure consistency and alignment with existing transplant system practices.

Response: We thank the commenters for their comment. We are finalizing these provisions without modification. However, we will take this feedback into consideration for future notice and comment rulemaking.

After consideration of the public comments we received, we are codifying in our

regulation at § 512.442(a)(2) that 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 to date on its website by the end of each relevant PY, as proposed without modification.

Additionally, we are finalizing our regulations at § 512.442(a)(3)(i) and (ii) that IOTA participants who perform living donor kidney transplants 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 without modification and 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 without modification.

We received no comments on our provisions 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) and therefore are finalizing these provisions as proposed without modification. We intend to further consider the cadence of updating this website and selection criteria. For IOTA participants who choose to post their selection criteria for evaluating patients for addition to their kidney transplant waitlist and living donors early in a given PY, we also encourage them to update their criteria again, should it change throughout the year.

(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). As stated in the 2025 Proposed Rule, we maintain our belief that this not only meets CMS requirements but also demonstrates transparency for the transplant community (90 FR 57614).

Adding to these provisions, we proposed 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 final rule, on the IOTA Model website (90 FR 57614). Specifically, for each PY, we indicated our intent to publish waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this final rule, for each IOTA participant on the IOTA Model website by the end of the second quarter of each subsequent PY. We proposed to finalize this requirement only if it was not redundant with other HHS guidance. We believed 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 believed 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 noted that this would supplement, not replace, the publication of selection criteria requirements in the IOTA Model.

We sought comments 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.

The following is a summary of the comments received 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 and our responses:

Comment: A commenter indicated that they were not opposed to publishing IOTA participant living donor selection criteria and kidney transplant waitlist selection criteria on the IOTA Model website but questioned the overall value of this action. The commenter expressed concern that making this information publicly available could enable insurers to access data limited to IOTA participants, potentially creating advantages or disadvantages for participating kidney transplant hospitals relative to non-participants.

Response: We appreciate the commenter's feedback and acknowledge the concern regarding the potential implications of publishing IOTA participant waitlist selection criteria and living donor selection criteria, particularly the possibility that insurers or other stakeholders could focus on information from only those kidney transplant hospitals participating in the IOTA Model. We understand the importance of ensuring that participation in the IOTA Model does not inadvertently create inequitable advantages or disadvantages for non-participants.

The intent of requiring centralized publication of these criteria is to promote transparency, consistency, and informed decision-making for patients and stakeholders. Publicly available information regarding selection criteria supports greater understanding of how candidates are evaluated and helps ensure clarity around the practices of IOTA participants. This transparency requirement is not intended to serve as a comparative performance tool or to elevate IOTA participants over non-participating kidney transplant hospitals.

Importantly, we note that this requirement pertains to the disclosure of selection criteria, not selective reporting of performance outcomes. Broader transplant hospital performance data remain subject to established reporting frameworks that apply uniformly across all transplant hospitals. As such, we respectfully disagree that posting this information on the IOTA Model website could allow insurer access to only IOTA participant data, thereby potentially creating unfair advantages or disadvantages for participating or non-participating institutions.

Furthermore, as described in the 2025 Proposed Rule (90 FR 57614) and in this section of this final rule, we believe the publication of this information on the IOTA Model website will address previous suggestions from commenters to provide this information in a centralized location (89 FR 96396). For these reasons, we are finalizing this provision without modification.

Comment: A commenter expressed opposition to the public posting of selection criteria on the IOTA Model website, citing concerns regarding the associated administrative burden and the absence of any substantive benefit.

Response: We thank the commenter for their feedback; however, we respectfully disagree that the requirement to publish selection criteria on the IOTA Model website would create additional administrative burden or provide limited benefit. As described in the 2025 Proposed Rule at 90 FR 57614 and in this section of this final rule, CMS intends to transfer the relevant selection criteria, as described and finalized in section II.B.4(a)(1) of this final rule, from individual IOTA participant websites to the IOTA Model website. Because the information is already publicly posted by IOTA participants pursuant to existing transparency requirements, we do not expect this provision to impose additional administrative burden.

We believe that making this information available through a centralized location will improve transparency and accessibility for patients, referring clinicians, and other stakeholders. As noted in the 2025 Proposed Rule (90 FR 57614) and discussed in this section of this final rule, this approach also responds to earlier stakeholder feedback requesting a centralized location for this information (89 FR 96396). As described in comment responses noted previously in this

section, we are finalizing this provision without modification. We will continue to welcome feedback from IOTA participants, patients, and the transplant community regarding the usefulness and implementation of this information on the IOTA Model website.

Comment: A commenter expressed opposition to publishing IOTA participant waitlist selection criteria and living donor selection criteria on the IOTA Model website. The commenter stated that patients typically seek this information directly from transplant hospital websites or through resources provided by the OPTN and expressed concern that relocating this information to a separate IOTA Model website could increase the potential for errors or inconsistencies in the information presented.

Response: We thank the commenter for their feedback and acknowledge the concern that patients often seek transplant hospital selection criteria directly from transplant hospital websites or through resources provided by the OPTN. However, as described in the 2025 Proposed Rule (90 FR 57614) and in this section of this final rule, publishing IOTA participant waitlist selection criteria and living donor selection criteria on the IOTA Model website is intended to supplement, not replace, these existing sources. IOTA participants will continue to publicly post this information on its individual kidney transplant hospital websites in accordance with the publication of selection criteria requirements as described and finalized in section II.B.4.a.(1) of this final rule. Centralized posting on the IOTA Model website is intended to improve accessibility and transparency by providing a single location where patients and referring clinicians may review and better understand the criteria used by IOTA participants to evaluate transplant candidates and potential living donors.

We also recognize the concern regarding potential errors or inconsistencies. CMS intends to transfer the relevant information directly from IOTA participant websites and requires IOTA participants to review and ensure their publicly posted criteria remain current by the end of each performance year. While the OPTN website provides valuable resources, it does not currently offer a centralized location where patients can easily review and compare transplant hospital

selection criteria. We believe this centralized posting helps address that gap and responds to prior stakeholder recommendations to make this information available in one location. Accordingly, as mentioned in comment responses noted previously in this section, we are finalizing this provision without modification.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing our proposals to publish IOTA participant waitlist selection criteria and the living donor selection criteria, as described and finalized in section II.B.4.a.(1). of this final rule, without modification, as outlined in section II.B.4.a(2) of the preamble of this final rule. Specifically, for each PY, we intend to publish IOTA participant waitlist selection criteria and the living donor selection criteria, as described and finalized in section II.B.4.a.(1). of the preamble of this final rule, for each IOTA participant on the IOTA Model website by the end of the second quarter of each subsequent PY. Not only does this meet CMS requirements, as previously discussed, but also demonstrates transparency for the transplant community. We will further consider the frequency and availability of this information on the IOTA Model website in future notice and comment rulemaking.

(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[59]; however, declining without disclosing the rationale to the patient may miss an important opportunity for shared decision-making.

As stated in the 2025 Proposed Rule at 90 FR 57614, after 3 years on the waiting list,

59 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.

approximately 27 percent of kidney transplant waitlist patients receive a deceased donor kidney transplant (DDKT), while 33 percent remain on the waitlist.[60] 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.[61,62] 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."[63] 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 noted in the 2025 Proposed Rule that 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 (90 FR 57615). One study conducted interviews with patients and nephrologists about this issue of organ offer transparency.[64] This study found that among 755 patient respondents surveyed, 64 percent expressed a preference to 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

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60 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

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

62 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

63 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

64 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.2025.01.013

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.[65] 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

65 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

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).

As stated in the 2025 Proposed Rule, based on the feedback we received, we proposed an alternative approach for the model (90 FR 57615). Specifically, for PYs 3 through 6 we proposed 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 proposed 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.
- Have accrued a minimum of 3 years of waiting time on the IOTA participant's waitlist.

We noted that our rationale for this proposal is explained further later in this section (90 FR 57615). We sought comment on our proposed definition of eligible IOTA waitlist beneficiaries at proposed § 512.402.

In the 2025 Proposed Rule, we proposed 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 (90 FR 57615). We stated that 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. We also stated that this proposed timeframe is designed to balance 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.

As stated at 90 FR 57615 of the 2025 Proposed Rule, for each 6-month period in which an organ offer is received and declined, we proposed 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)[66] 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.

66 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.

- The refusal reason(s)[67] why offers were declined based off the OPTN refusal codes in plain language.

- Of the deceased donor kidney organ offers declined for that eligible IOTA waitlist beneficiary how many of those kidneys were transplanted in another kidney transplant patient, as defined at § 512.402.

- Potential avenues to accelerate access to transplant (for example, exploring living donation, being waitlisted at multiple kidney transplant hospitals, reviewing transplant organ offer acceptance criteria or ensuring they meet and maintain the patient criteria for their chosen kidney transplant hospital(s), such as adhering to weight loss recommendations).

We believed 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 (90 FR 57616). We noted 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:

As stated at 90 FR 57616 in the 2025 Proposed Rule, 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 the

67 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.

2025 Proposed Rule in Fall 2025 until the start of PY 3 on July 1, 2027, to implement the necessary processes to implement these notification requirements.

Next, we believed that this updated provision that we proposed 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 (90 FR 57616). For example, in the 2025 Proposed Rule we proposed 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 final 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 further stated in the 2025 Proposed Rule that 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 (90 FR 57616).

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 (90 FR 57616). 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 sought comment on the alternative considered.

As stated in the 2025 Proposed Rule, 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 (90 FR 57616). 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 final 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 (90 FR 57616). 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 (90 FR 57616). 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 (90 FR 57616). 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) (90 FR 57616). We thought 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, we stated that 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 recognized that requiring IOTA participants to use a CMS-provided notification template presents certain considerations that merit evaluation. While standardization offers benefits, we recognized 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, we stated that 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 did not propose to provide a standardized notification template that IOTA participants would be required to use, we sought 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 sought 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 proposed 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 (90 FR 57617). We proposed at § 512.442(b)(2)(i) IOTA participants must give eligible IOTA waitlist beneficiaries the opportunity to opt out of receiving this notification. We proposed 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.

In the 2025 Proposed Rule at 90 FR 57617, we also proposed 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 proposed 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 (90 FR 57617).

As described at 90 FR 57617 in the 2025 Proposed Rule, 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 the 2025 Proposed Rule we stated 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 (90 FR 57617). 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 believed recording only when a notification was sent does not confirm that the information reached the eligible IOTA waitlist beneficiary. We also believed 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, we stated that 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, we stated that 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 sought comment on our proposals to provide transparency into kidney transplant organ offers at proposed § 512.442(b). We also sought comment on the alternatives considered.

The following is a summary of the public comments received on all of the transparency into kidney transplant organ offers proposals and alternatives considered set out in this section and our responses:

Comment: Several commenters requested that CMS further define what constitutes "3 years of waiting time" on an IOTA participant's waitlist, noting that there are multiple mechanisms by which waiting time may be accrued and that additional clarification would be helpful for consistent implementation.

Response: We thank the commenters for their feedback. After consideration for the concerns raised by commenters, we are not finalizing the proposed transparency into kidney transplant organ offers provision at § 512.442(b), and therefore are not finalizing the proposed definition of eligible IOTA waitlist beneficiaries. We remain committed to advancing transparency in a manner that balances patient benefit and operational feasibility and will continue to engage with transplant stakeholders to identify potential alternative approaches that may be considered in future notice and comment rulemaking.

Comment: A commenter expressed opposition to the provision that organ offer information would be required to be shared exclusively with IOTA waitlist patients who have accrued three years of wait time on the IOTA participant's waitlist.

Response: We thank the commenters for their comment. As mentioned in comment responses noted previously, in response to the comments we received, we will not be finalizing the proposed transparency into kidney transplant organ offers provision. As such, we will not be

finalizing the definition of eligible IOTA waitlist beneficiaries.

Comment: A commenter expressed support for CMS's consideration of a standardized template for IOTA participants to use in providing transparency into kidney transplant organ offers, including the elements specified at proposed § 512.442(b)(1)(i)(A) through (F). The commenter further recommended that any such template be pre-populated to the greatest extent possible to minimize administrative burden on IOTA participants.

Response: We appreciate the commenter's feedback. As described in comment responses noted previously in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time.

Comment: A commenter expressed interest in the development of a standardized template for transparency into kidney transplant organ offers and indicated a willingness to collaborate with CMS and the patient community to support its design and implementation.

Response: We thank the commenter for their interest in the development of a standardized template for transparency into kidney transplant organ offers and willingness to collaborate with CMS and the patient community to support its design and implementation. However, as described in comment responses noted previously in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time.

Comment: Numerous commenters expressed strong support for increasing transparency in the transplant system but urged CMS not to finalize the proposed requirement at § 512.442(b) to notify eligible IOTA waitlist beneficiaries of declined organ offers every six months. Many commenters stated that the data needed to support these notifications are not available in a single source and would require extensive manual review, resulting in significant administrative burden and diversion of clinical resources away from patient care. Commenters emphasized that most declined offers are based on clinical suitability or organ quality and noted that communicating these complex, patient-specific decisions could generate additional patient questions, further increasing workload. Several commenters asserted that CMS underestimated the time and

resources required, and raised concerns that compliance costs, without additional funding, could strain transplant programs or lead to scaling back services.

Commenters also raised concerns about patient impact. Some commenters noted that their programs already emphasize shared decision-making and patient education, and cautioned that presenting complex and nuanced organ offer data could create confusion, distress, or erosion of trust. Other commenters stated that the decision to accept or decline an organ is highly individualized and involves numerous clinical factors that may be difficult for patients to interpret meaningfully. A commenter highlighted that even transplant professionals face challenges in attributing a single reason for organ declines, citing the complexity of decision-making and ongoing efforts to refine OPTN refusal codes. Commenters expressed concern that providing large volumes of technical information without sufficient context could undermine, rather than enhance, patient understanding and engagement.

Several commenters recommended alternative approaches to transparency that may be more feasible and meaningful. For example, a commenter suggested providing patients with individualized estimates of wait time based on their characteristics, while another recommended CMS focus oversight on transplant hospitals with significantly higher refusal rates. Other commenters proposed patient-initiated access to aggregate and de-identified data, or leveraging centralized OPTN resources to provide standardized information. Across comments, there was a consistent recommendation that CMS collaborate with the transplant community to develop transparency approaches that balance patient benefit with operational feasibility.

Response: We thank the commenters for their concerns. Due to the many concerns received, we recognize that notifying eligible IOTA waitlist beneficiaries, as described in this section of this final rule, regarding volume and reason for organ decline could be very burdensome to IOTA participants and their staff in PY 3 since this would be a new requirement and there is not current infrastructure or database resources to aid in minimizing burden on IOTA participants. We need more time to better identify how we can increase transparency of the

organ offer process for transplant recipients with the help of the transplant community. Minimizing administrative burden for kidney transplant hospitals while maximizing meaningful communication with beneficiaries will be key in these discussions as the transplant community participates in this dialogue. Subsequently, in response to these comments and those raised in this section, we will not be finalizing our regulation at proposed § 512.442(b), which required that eligible IOTA waitlist beneficiaries, as defined at proposed § 512.402 on the IOTA participant's waitlist be notified at least once every 6 months about the number of times an organ is declined. Additionally, as mentioned in comment responses noted previously in this section, we will not be finalizing the proposed definition of eligible IOTA waitlist beneficiary at this time. We look forward to engaging in conversation with transplant stakeholders to understand additional transparency opportunities to mutually meet patient and provider goals, prior to potentially revisiting this in future notice and comment rulemaking.

Comment: A commenter expressed support for the proposal to notify eligible IOTA waitlist beneficiaries with at least 3 years of waiting time of the number of times an organ is declined on their behalf every six months, stating that the requirement would not be overly burdensome. However, the commenter recommended that CMS consider limiting the scope of reported organ offers to those within a specified threshold on the match run to improve relevance and feasibility.

Response: We thank the commenter for their support and recommendation. We will not be finalizing the proposed transparency into kidney transplant organ offer provision, as described in comment responses noted previously in this section, but may consider this idea in future notice and comment rulemaking as we continue to assess ways to increase transparency and maximize meaningful communication while minimizing administrative burden for kidney transplant hospitals.

Comment: A commenter expressed support for notifying eligible IOTA waitlist beneficiaries of the number of times an organ is declined on their behalf, asserting that such

transparency would help ensure that care aligns with beneficiaries' preferences. However, the commenter recommended excluding organs that are ultimately discarded from these notifications. The commenter also questioned the proposed threshold of requiring at least three years of accrued waiting time, describing it as arbitrary and suggesting that notifications begin earlier, while acknowledging the need to balance transparency with feasibility. The commenter further emphasized the importance of ongoing patient education beginning at the time of waitlist placement and recommended linking notifications to real-time communication support to reduce potential anxiety. The commenter also disagreed that eligible IOTA waitlist beneficiaries would be overwhelmed by a high volume of offers, stating this does not reflect typical patient experience. Additionally, the commenter advocated for the centralization of reporting through the establishment of a personal organ offer portal administered by the OPTN, which would provide standardized information and afford greater patient autonomy.

Response: We appreciate the commenters' support of our objective to enhance transparency and acknowledge their thoughtful recommendations regarding patient empowerment, including proposals for enhanced educational initiatives and the establishment of a centralized reporting portal. As mentioned in comment responses noted previously in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. We intend to continue engaging with the transplant community to identify appropriate approaches for future transparency initiatives, including consideration of which types of organ offers may be appropriate to include or exclude in such reporting.

Comment: A commenter expressed support for increased transparency, stating that patients often lack visibility into significant decisions made by transplant hospitals on their behalf. The commenter recommended that patients be informed of organ offer declines and provided with educational information regarding organ quality and anticipated outcomes to support understanding and engagement in decision making.

Response: We thank the commenter for their support and for emphasizing the

importance of informing patients about organ offer declines and related considerations. We agree that transparency and patient education are important to support informed decision making and patient engagement. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. We remain committed to exploring approaches to enhance transparency and patient understanding in collaboration with patients, providers, and the broader transplant community.

Comment: A commenter expressed support for the proposed transparency into kidney transplant organ offer notification requirements, particularly when combined with patient reported outcome measures to promote patient centered care. However, the commenter raised concerns regarding the proposed threshold of three years of accrued waiting time for eligible beneficiaries to receive notifications and suggested that CMS consider shorter or tiered waiting time thresholds to allow earlier access to this information.

Response: We thank the commenter for their support and feedback and acknowledge the concern regarding limiting organ offer notifications to eligible IOTA waitlist beneficiaries with at least three years of accrued waiting time, particularly given variation in wait times and the potential for patients to receive organ offers earlier. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking.

Comment: A commenter expressed support for the requirement that IOTA participants provide notifications to eligible IOTA waitlist beneficiaries regarding declined organ offers, noting that such measures would serve to enhance transparency. However, the commenter cautioned that implementation must be undertaken thoughtfully to avoid causing undue anxiety or confusion among eligible IOTA waitlist beneficiaries. The commenter recommended providing information through periodic, aggregated summaries rather than real-time notifications, focusing on clinically meaningful offers, and including standardized, plain-

language explanations. The commenter further stated that transparency efforts should aim to empower patients by pairing such information with ongoing education about the complexity of the organ offer decision-making process, thereby supporting patient understanding and trust.

Response: We thank the commenter for their support of CMS' efforts to enhance transparency and for their thoughtful recommendations regarding implementation. We agree that transparency initiatives should be designed to support patient understanding and avoid unnecessary confusion or anxiety, and we appreciate the suggestions to use periodic summaries, focus on clinically meaningful offers, and incorporate plain language explanations and education. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A commenter expressed support for the proposal to retrospectively share declined organ offer information with eligible IOTA waitlist beneficiaries on a semi-annual basis, emphasizing that they should have access to this information if they choose. However, the commenter opposed limiting eligibility to IOTA waitlist patients who had accrued a minimum of 3 years of waiting time on an IOTA participants waitlist, noting that patients may begin receiving organ offers within weeks of listing and that prolonged time on dialysis may reduce transplant opportunities. The commenter also raised concerns about the potential administrative and time burden on providers, suggesting that billing mechanisms be considered to support these complex patient discussions. To mitigate burden on IOTA participants, the commenter proposed alternative approaches, such as limiting shared data to organs that were ultimately transplanted or restricting disclosure to a certain point in the match run. The commenter further emphasized the importance of leveraging technology to automate data sharing and recommended that this information also be provided to the patient's referring nephrologist to support shared decision-making. The commenter cautioned that careful implementation would be necessary to ensure

that increased transparency enhances patient trust and understanding rather than causing confusion.

Response: We appreciate the commenter's thoughtful feedback, including their support for the principle that patients have a right to their health data and their insightful suggestions regarding implementation. We acknowledge the observation that the proposed accrued a minimum of 3 years waiting time on the IOTA participant's waitlist could potentially exclude those who receive offers early in their journey, and we agree that any transparency initiative must be carefully designed to foster trust. Additionally, we recognize the commenter's emphasis on mitigating IOTA participant burden through recommendations such as automation, the establishment of billing codes, and the sharing of information with referring nephrologists to facilitate shared decision-making. As described in the comment responses within this section, we are not finalizing the proposed transparency into kidney transplant organ offers provisions at this time. However, we consider this to be an important area of consideration and will take this comment into account in future notice and comment rulemaking as appropriate.

Comment: A commenter expressed support for the proposal to notify eligible IOTA waitlist beneficiaries, on at least a semiannual basis, of the number of organ offers declined on their behalf while on the IOTA participant's waitlist. However, the commenter recommended that CMS consider excluding kidney transplant organ offers that were ultimately discarded from these notifications. The commenter also suggested that CMS explore the development of individualized organ offer filters to reduce the volume of clinically inappropriate offers and alleviate operational burden for IOTA participants.

Response: We thank the commenter for their feedback and for their support of efforts to improve transparency into kidney transplant organ offers. We appreciate the recommendation to reduce the number of clinically inappropriate organ offers through approaches such as individualized organ offer filters, and we agree that such strategies may help alleviate operational burden for IOTA participants while improving the efficiency of the organ offer process. As

described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A few commenters expressed support for the goal of increasing transparency through the proposed transparency into kidney transplant organ offers notification requirements, noting the potential to enhance patient empowerment. However, the commenters emphasized that any such requirements should be operationally feasible for IOTA participants and designed in a manner that is meaningful and helpful for patients.

Response: We thank the commenters for their feedback. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A commenter expressed appreciation for the flexibility in the proposed transparency into kidney transplant organ offer notification delivery options.

Response: We thank the comment for their support.

Comment: A commenter recommended that CMS not finalize the proposed transparency into kidney transplant organ offers requirements, citing concerns regarding administrative burden, potential disruption to existing clinical protocols, limited patient benefit, lack of clarity regarding which organ offers would need to be communicated, and the overall complexity of organ offer decision-making.

Response: We thank the commenter for their recommendation. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A commenter expressed strong opposition to the proposed organ offer notification requirement, asserting that challenges in the transplant system stem primarily from the organ allocation framework rather than a lack of patient communication. The commenter stated that requiring IOTA participants to explain complex, multifactorial reasons for declining organ offers would impose significant burden and may lead to patient confusion. As an alternative, the commenter recommended a patient-centered approach in which eligible IOTA waitlist beneficiaries define their preferences regarding transplant longevity and acceptable waiting time, which could then be incorporated into a statistical matching model to better align organ allocation with individual patient goals.

Response: We thank the commenter for their comment. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A commenter expressed opposition to the proposed organ offer notification requirement, stating that the criteria used to determine organ acceptance are highly complex, even for experienced physicians. The commenter further noted that the effort required to communicate this information, as well as the potential for patient confusion, may outweigh any anticipated benefits.

Response: We thank the commenter for their comment. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A commenter recommended that CMS collaborate with HRSA to develop a standardized format for the proposed transparency into kidney transplant organ offers notifications, noting that such an approach could reduce administrative burden and eliminate the need for delivery verification methods such as certified mail or read receipts.

Response: We thank the commenter for their recommendation. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

Comment: A commenter observed that several proposed transparency requirements, including notifications of organ offer declines and waitlist status changes, depend upon the accurate identification of CMS-attributed beneficiaries. The commenter urged CMS to refrain from imposing requirements that would compel hospitals to duplicate information already maintained within OPTN systems. The commenter recommended that CMS securely transmit relevant beneficiary-attribution lists to the OPTN to facilitate the automated generation of standardized, patient-specific reports for Medicare beneficiaries. The commenter asserted that this approach would enhance accuracy, reduce the need for manual reconciliation by IOTA participants, standardize notification formats, and substantially diminish administrative burden. The commenter further suggested that such reports could be distributed directly by CMS or made accessible through a secure OPTN-developed patient portal, and encouraged collaboration among CMS, HRSA, and the OPTN to leverage existing data expertise. The commenter maintained that centralized reporting and distribution would promote consistency, reduce variation across institutions, and advance the stated goals of the model.

Response: We thank the commenter for their comment. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking as appropriate.

After consideration of public comment, for the reasons set forth in this rule, we are not finalizing our proposed provisions for transparency into kidney transplant organ offers at § 512.442(b).

(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.

As described at 90 FR 57617 in the 2025 Proposed Rule, 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 the 2025 Proposed Rule, we aimed 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 proposed 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 sought comment on our proposal at proposed § 512.442(c) to clarify the meaning of transplant organ offer acceptance criteria. We also sought

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 proposed 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 (90 FR 57618). We proposed 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 proposed 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 (90 FR 57618). We sought comment on these proposed requirements at proposed § 512.442(c)(1)(i) and (ii).

Lastly, as stated in the proposed rule at 90 FR 57618, to facilitate compliance monitoring, we proposed 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 sought comment on these proposed documentation requirements at proposed § 512.442(c)(2)(i) through (iii).

The following is a summary of the public comments received on all of the review of acceptance criteria proposals and alternatives considered set out in this section and our responses:

Comment: A few commenters expressed support for CMS's efforts to provide clarification regarding the transplant organ offer acceptance criteria requirement, particularly with respect to ensuring compliance and oversight; however, they requested additional clarification on certain aspects of the provision. In particular, a commenter conveyed appreciation for the clarification but requested further specifications regarding documentation requirements and expectations to promote consistency across IOTA participants.

Another commenter expressed support for the clarification but requested that CMS delineate the minimum criteria that would be required to fulfill this update. Furthermore, the commenter indicated that, to effectively implement the proposed review of acceptance criteria requirements at § 512.442(c), as described in this section of this final rule, the existing specific informed consent processes for KDPI greater than 85 percent or high-risk organs could be updated on a semiannual basis, thereby aligning current OPTN policy with these requirements.

The same commenter also suggested that CMS consider strictly requiring a discussion regarding declined categories of organs every six months, rather than requiring a review of organs for which the patient is both enrolled and not enrolled to receive.

Response: We thank the commenters for their support of CMS's efforts to clarify the current review of acceptance criteria review requirement and for recognizing the importance of clear standards to support compliance and oversight. We appreciate the commenters' requests for additional specificity regarding documentation expectations and minimum criteria for implementing the provision. As described in the 2025 Proposed Rule at 90 FR 57617 and this section of this final rule, the requirement at § 512.442(c) clarifies that IOTA participants must review individualized transplant organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries at least once every six months while the patient remains on the waitlist, unless the patient declines the review. The provision also requires IOTA participants to document in the patient's medical record that the review occurred, the date of the review, and the method by which the review was conducted. We believe that these documentation elements provide a clear and consistent framework for compliance while allowing flexibility for IOTA participants to integrate the review into existing clinical workflows and patient communication practices.

We also appreciate the commenter's suggestion that CMS delineate minimum criteria for fulfilling the requirement and align the review with existing OPTN informed consent processes for kidneys with a KDPI greater than 85 percent or other high-risk organs. While we recognize that IOTA participants may choose to incorporate such discussions into their existing informed consent or patient education processes, the purpose of this provision is broader: to ensure that patients periodically review their individualized acceptance parameters for categories of organ offers they may be willing to accept for transplantation. Because transplant candidacy, patient preferences, and clinical circumstances may change over time, we believe that a comprehensive review of a patient's transplant organ offer acceptance criteria, as defined in this section of this

final rule, better supports shared decision-making and informed patient engagement, rather than limiting the discussion to specific categories such as high-KDPI or previously declined organs.

For similar reasons, we do not believe it is appropriate to require that the review of acceptance criteria focus solely on declined categories of organs. We note that the intent of the requirement is to ensure that IOTA waitlist patients who are Medicare beneficiaries periodically reassess the full range of organ offer categories they may be willing to accept, including those they have elected to accept as well as those they have chosen not to accept. We believe that this broader discussion allows IOTA waitlist patients who are Medicare beneficiaries and clinicians to revisit preferences, consider evolving clinical circumstances, and ensure that acceptance parameters remain aligned with the patient's current goals and medical status. Accordingly, while IOTA participants may incorporate elements of existing informed consent discussions or other patient education processes into this review, we continue to believe that the flexibility provided in the regulation appropriately balances clarity, patient engagement, and operational feasibility. For these reasons, we are finalizing the proposed review of acceptance criteria requirements at § 512.442(c) and the definition of transplant organ offer acceptance criteria at § 512.402 without modification. We direct readers to section II.B.4.a(4) of this final rule for a full discussion of the proposed review of acceptance criteria documentation requirements and specifications.

Comment: A commenter opposed CMS's proposed transparency updates for the IOTA Model, stating that the provisions would introduce substantial administrative burden and associated costs. The commenter specifically identified the requirement for a semiannual review of individualized transplant organ offer acceptance criteria for IOTA waitlist patients who are Medicare beneficiaries as particularly labor-intensive, suggesting that implementation could necessitate additional staffing and financial resources that are not currently supported. The commenter further cautioned that the diversion of resources to fulfill this requirement could adversely affect patient care by delaying organ allocation processes and elevating organ risk. As

an alternative, the commenter recommended that CMS provide transplant hospitals, particularly those participating in mandatory models, with greater flexibility in implementation, allowing experienced transplant programs to achieve model objectives without being constrained by additional regulatory requirements.

Response: We thank the commenter for their feedback and acknowledge the concerns raised regarding potential administrative burden. However, we believe that this discussion is necessary to ensure that IOTA waitlist patients who are Medicare beneficiaries understand and maintain ongoing consent to the transplant organ offer acceptance criteria applicable to them.

Comment: A commenter expressed concerns regarding both the existing requirement to review transplant organ offer acceptance criteria, as finalized in the 2024 Final Rule (89 FR 96402), which requires that such criteria be reviewed with IOTA waitlist patients who are Medicare beneficiaries at least once every six months, and the proposed clarification that such reviews must address individualized transplant organ offer acceptance criteria, as described in this section of this final rule. Specifically, the commenter questioned the clarification that the review must focus on individualized transplant organ offer acceptance criteria rather than transplant hospital level acceptance criteria. The commenter asserted that the implementation of individualized reviews would impose substantial administrative and operational burdens on transplant hospitals, particularly in the absence of additional resources or funding to support the requisite time and staffing necessary to conduct and document these discussions. The commenter further argued that the associated costs would outweigh the anticipated benefits. Additionally, the commenter expressed concern that CMS may have underestimated the time required to perform these individualized reviews and suggested that such discussions could inadvertently mislead IOTA waitlist patients who are Medicare beneficiaries, given that organ suitability is multifactorial in nature and may change over time in response to evolving clinical circumstances.

Response: We thank the commenter for their feedback; however, we respectfully

disagree that this requirement undermines clinical judgment. The intent of this provision, as described and finalized at § 512.442(c) of this final rule, is to create a structured opportunity to facilitate and document the individualized discussions that are central to sound clinical practice, ensuring that an IOTA waitlist patient who is a Medicare beneficiary's understanding of and preferences regarding transplant organ offer acceptance criteria, as defined and finalized at § 512.402 of this final rule, are revisited over time as clinical circumstances and patient perspectives may evolve throughout the transplant waiting period. We believe that this semiannual review of acceptance criteria requirement supports patient engagement and informed decision-making by ensuring that these discussions occur consistently and are appropriately documented, and is intended to complement, rather than replace, ongoing clinical conversations between transplant teams and IOTA waitlist patients who are Medicare beneficiaries, reinforcing shared decision-making and strengthening the patient-provider relationship throughout the transplant journey.

Comment: A commenter expressed opposition to the proposed review of acceptance criteria documentation requirements, characterizing them as overly rigid. As an alternative, the commenter recommended that IOTA participants provide general information regarding transplant hospital level organ offer acceptance criteria to all IOTA waitlist patients, while issuing individualized notifications only to those IOTA waitlist patients whose acceptance criteria differ from the transplant hospital's general criteria. The commenter suggested that this approach could streamline communication and potentially eliminate the need for an opt out process for the review requirement.

Response: We thank the commenter for suggesting an alternative approach to streamline communication with IOTA waitlist patients, specifically by providing general transplant hospital-level organ offer acceptance criteria to all IOTA waitlist patients and issuing individualized notifications only when an IOTA waitlist patient's criteria differ. However, the purpose of the review of acceptance criteria provision is to promote individualized, patient-

centered discussions regarding transplant organ offer acceptance criteria rather than to disseminate general information applicable to all patients. Requiring IOTA participants to periodically review these criteria with each IOTA waitlist patient who is a Medicare beneficiary ensures that patients have a structured opportunity to revisit their personal preferences and understanding of the categories of organ offers they may be willing to accept, which may change over time based on evolving clinical circumstances and patient priorities. Documenting that this review was offered and whether the IOTA waitlist patient who is a Medicare beneficiary chose to participate in or decline the review is therefore necessary to demonstrate that this individualized engagement has occurred.

We also note that the alternative approach described by the commenter could result in additional administrative complexity. Under such an approach, IOTA waitlist patients whose acceptance criteria differ from transplant hospital-level criteria could potentially receive multiple communications, which may increase rather than reduce documentation and administrative workload. In addition, maintaining the ability for IOTA waitlist patients who are Medicare beneficiaries to decline participation in these reviews remains an important beneficiary protection. The opt-out provision, as described and finalized in this section of this final rule at § 512.442(c)(1)(i) and (ii), ensures that patients retain autonomy in deciding whether to participate in periodic reviews of their transplant organ offer acceptance criteria while preserving the opportunity for ongoing engagement. As described in comment responses noted previously in this section, we are finalizing this provision without modification. However, we appreciate the commenter's perspective and will consider this recommendation in future notice and comment rulemaking as appropriate.

Comment: A commenter expressed concern that the requirement to conduct periodic reviews of transplant organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries may prove burdensome and potentially confusing for these patients. The commenter asserted that discussing highly technical donor organ offer acceptance criteria during

mandated reviews could heighten patient anxiety and may not meaningfully enhance patient comprehension. The commenter emphasized that substantive discussion and documentation of organ offer acceptance preferences should occur principally at the time of placement on a waitlist or when specific consent decisions are modified.

The commenter further indicated that, given the complexity of organ offer acceptance criteria and their susceptibility to change based on evolving clinical circumstances, requiring standardized periodic patient reviews could oversimplify clinical judgment, engender confusion regarding options that may not be clinically appropriate, and impose a significant administrative burden on IOTA participants. The commenter recommended that retrospective or recurring reviews of these criteria be eliminated and proposed instead that CMS collaborate with HRSA and the OPTN to develop centralized educational materials pertaining to organ offer acceptance criteria in order to promote consistency, transparency, and patient understanding.

Response: We thank the commenter for their thoughtful feedback. We wish to clarify that the intent of this requirement is not to mandate a technical or exhaustive review of every donor organ acceptance criterion, but rather to establish a recurring opportunity for a high-level, individualized discussion that helps ensure an IOTA waitlist patient who is a Medicare beneficiary maintains an up-to-date understanding of their transplant organ offer acceptance criteria and preferences during what may be an extended waitlist period. Because transplant organ offer acceptance criteria, as defined and finalized in this section of this final rule at § 512.402, and patient circumstances may evolve over time, we believe that periodic discussion beyond the initial conversation at the time of being added to a waitlist supports patient engagement and informed decision-making. These reviews are intended to complement, not replace, the clinical judgment exercised by transplant teams at the time of an organ offer.

We also agree that centralized educational materials could support patient understanding and serve as a useful foundation for these discussions. While we are finalizing the proposed review of acceptance criteria requirement at § 512.442(c) without modification, as described in

comment responses noted previously in this section, we intend to explore opportunities with HRSA to expand centralized educational resources related to transplant organ offer acceptance criteria and, if appropriate, will propose alternative or updated policies in future notice and comment rulemaking.

Comment: A commenter expressed appreciation for the provision allowing IOTA waitlist patients who are Medicare beneficiaries to opt out of the review of transplant organ offer acceptance criteria. However, the commenter suggested that administrative burden could be reduced and patient autonomy enhanced if IOTA waitlist patients who are Medicare beneficiaries were permitted to select different intervals for receiving these notifications, such as every six months or annually, rather than adhering to a single standardized review timeframe.

Response: We appreciate the commenter's support for the opt out provision and their suggestion regarding allowing IOTA waitlist patients who are Medicare beneficiaries to select different intervals for receiving notifications. However, as described in comment responses noted previously in this section, we are finalizing the review of acceptance criteria requirement without modification. We believe that maintaining a consistent review interval supports clear expectations for IOTA participants and ensures that patients have regular opportunities to revisit their transplant organ offer acceptance criteria. However, we appreciate the commenter's recommendation and will consider this suggestion in future notice and comment rulemaking, particularly if monitoring of this provision indicates that the current review of acceptance criteria frequency results in unintended administrative or operational consequences.

Comment: A few commenters expressed concern for the proposed review of acceptance criteria provisions. A commenter expressed concern that the requirement to document a patient's decision to decline the review of acceptance criteria every six months would create administrative burden and reduce time available for clinical care. This commenter suggested that this process could require individualized outreach prior to each notification cycle in order to confirm whether the IOTA waitlist patient who is a Medicare beneficiary wished to participate or

decline the review.

Another commenter similarly noted that this requirement effectively creates a notification obligation both for conducting the review and for documenting a IOTA waitlist patient who is a Medicare beneficiary's decision to opt out. To reduce administrative burden, the commenter suggested allowing IOTA waitlist patients who are Medicare beneficiaries to opt out once on a permanent basis if they choose not to participate in these reviews.

Response: We thank the commenters for their feedback and acknowledge the concerns raised regarding potential administrative burden associated with documenting an IOTA waitlist patient who is a Medicare beneficiary's decision to decline the review of acceptance criteria. However, as described in comment responses noted previously in this section, the intent of this provision is to ensure that IOTA waitlist patients who are Medicare beneficiaries are regularly offered the opportunity to engage in a meaningful discussion regarding their transplant organ offer acceptance, as defined and finalized in this section of this final rule at § 512.402, preferences. We believe that documenting whether an IOTA waitlist patient who is a Medicare beneficiary chooses to participate in or decline the review is a necessary component of demonstrating that this important patient engagement opportunity was offered.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions at § 512.442(c), § 512.442(c)(1)(i) through (ii)(B), and § 512.442(c)(2) without modification. We are also finalizing, as proposed, the definition of transplant organ offer acceptance criteria at § 512.402 without modification.

(5) Change in Waitlist Status

As described in the 2025 Proposed Rule at 90 FR 57618, 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)). We stated that 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. We also stated that these notification requirements serve as a crucial mechanism to ensure transparency and protect patient interests throughout the transplant waiting period.

In the 2025 Proposed Rule, we stated that patients on the transplant waiting list are designated as either "active" or "inactive" (90 FR 57618). 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 (90 FR 57618). 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.[68] 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.[69,70,71,72,73] Any of these concerns may prompt a temporary inactivation until the problem is resolved,

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68 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.

69 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*

70 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*

71 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

72 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

73 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*

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.[74,75] 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.[76,77,78,79]

We also stated in the proposed rule at 90 FR 57619 that numerous research studies have demonstrated that kidney transplant waitlist patients frequently experience confusion and

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74 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*

75 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*

76 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*

77 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*

78 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*

79 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*

knowledge deficits regarding the transplant evaluation and listing process.[80,81,82,83,84,85,86,87] 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[88,89,90,91], a belief that they are already on the waiting list[92,93,94], unawareness that tests must be repeated[95,96], and misunderstanding about being placed on inactive status on the waiting

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80 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*

81 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*

82 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*

83 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

84 Patzer, R. E., Perryman, J. P., Pastan, S., Amaral, S., Gazmararian, J. A., Klein, M., Kutner, N., & McClellan, W. M. (2012). Impact of a patient education program on disparities in kidney transplant evaluation. *Clinical journal of the American Society of Nephrology:CJASN, 7*(4), 648–655. *https://doi.org/10.2215/CJN.10071011*

85 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*

86 Park, C., Jones, M.-M., Kaplan, S., Koller, F. L., Wilder, J. M., Boulware, L. E., & McElroy, L. M. (2022). A scoping review of inequities in access to organ transplant in the United States. *International Journal for Equity in Health, 21*(1). *https://doi.org/10.1186/s12939-021-01616-x*

87 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*

88 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

89 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*

90 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

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

92 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*

93 Gillespie, A., Hammer, H., Lee, J., Nnewihe, C., Gordon, J., & Silva, P. (2011). Lack of listing status awareness: results of a single-center survey of hemodialysis patients. *American journal of transplantation:official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 11*(7), 1522–1526. *https://doi.org/10.1111/j.1600-6143.2011.03524.x*

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

95 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*

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

list[97,98]. 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.[99,100,101,102,103,104]

Furthermore, as described in the 2025 Proposed Rule at 90 FR 57619, 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).[105,106] We stated that 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.

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97 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*

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

99 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*

100 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*

101 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*

102 Stewart, D., Mupfudze, T., & Klassen, D. (2023b). Does anybody really know what (the kidney median waiting) time is? *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 23*(2), 223–231. *https://doi.org/10.1016/j.ajt.2022.12.005*

103 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*

104 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*

105 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/*

106 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.

As such, we proposed 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 (90 FR 57619). Specifically, we proposed, 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 and that would impact their ability to receive an organ offer (that is, from active to inactive). We sought comment on our proposal to add a change in waitlist transparency requirement at proposed § 512.442(d)(1)(i).

As described in the 2025 Proposed Rule, we considered but did not propose requiring IOTA participants to also notify their IOTA waitlist patients who are Medicare beneficiaries whenever their status changes from inactive to active in addition to whenever their waitlist status changes from active to inactive (90 FR 57620). We believed 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 recognized 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, we stated that 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 did not propose to also require IOTA participants to notify their IOTA waitlist patients who are Medicare beneficiaries whenever their status from inactive to active, we sought 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.

At 90 FR 57620 of the 2025 Proposed Rule, we proposed 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 sought 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.

At 90 FR 57620 of the 2025 Proposed Rule, we proposed 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).

As described in the 2025 Proposed Rule, we considered alternative methodologies for implementing this provision (90 FR 57620). 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 final 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 final 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 (90 FR 57620). 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 sought public comment on our proposed change in waitlist status delivery method and timeline requirements at proposed § 512.442(d)(1)(iii)). We also sought comment on the alternatives considered.

In the 2025 Proposed Rule, we also proposed 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 (90 FR 57620):

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

Additionally, we proposed 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[107], the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient who is a Medicare beneficiary.

We stated that this notification timeframe conforms with the current timeframe at § 482.94, however, we solicit public comment on alternative timeframes that may be appropriate. We also stated that 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 proposed to finalize these requirements only if they are not redundant with other HHS guidance.

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

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107 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.

In the 2025 Proposed Rule we stated that 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 (90 FR 57621). However, we stated our belief that kidney transplant waitlist patients should be aware of these situations and the impact it has on their ability to receive an offer. Additionally, we stated that 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. We stated that, 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 believed 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, in the 2025 Proposed Rule, we stated that 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 (90 FR 57621). We stated that 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 noted 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.

The following is a summary of the comments we received on the provisions proposed and alternatives considered set out in this section and our responses:

Comment: Numerous commenters expressed support for the proposal to add a change in waitlist transparency requirement. For example, many commenters emphasized that consistent and timely notification is critical because a patient's waitlist status directly affects their eligibility to receive organ offers and is among the most important pieces of information for understanding their transplant prospects. Another commenter indicated that current notification practices vary across transplant hospitals and agreed that establishing a clear requirement would promote greater transparency, improve patient awareness of transplant status, and help ensure patients are promptly informed of changes that impact their opportunity for transplantation.

Response: We thank the commenters for their support of the proposal to add a change in waitlist transparency requirement, as described in this section of this final rule. We agree that a patient's waitlist status is critical information because it directly affects eligibility to receive organ offers and may significantly influence a patient's understanding of their transplant opportunities. We also agree that timely and consistent notification of changes in waitlist status promotes transparency, supports patient awareness, and helps ensure that patients are informed when their ability to receive an organ offer is affected.

We further acknowledge commenters' observations that notification practices may vary across transplant hospitals. We believe that establishing a clear requirement will promote greater consistency in communication, improve patient understanding of transplant status, and help ensure that patients are promptly notified of changes that may affect their opportunity for transplantation. For these reasons, we are finalizing the change in waitlist transparency requirement as proposed. We note that a full discussion on the comments we received about the proposed change in waitlist status requirements and our responses are discussed later in this section.

Comment: Many commenters opposed the proposal to add a change in waitlist status provision, citing concerns about duplication, operational burden, and potential patient confusion. They noted that transplant hospitals already maintain established, CMS-governed processes for notifying patients of waitlist status changes, including active-to-inactive transitions, and argued that imposing additional IOTA Model-specific requirements would be redundant and unnecessary, particularly where IOTA participants already notify all waitlisted patients as part of standard practice. Commenters further asserted that the proposal would create significant administrative and operational challenges, especially for IOTA participants with large waitlists or frequent status changes, potentially requiring workflow redesign, additional staffing, and new expenditures. They expressed concern that these compliance obligations could divert resources from direct patient care, delay transplant services, and strain clinical teams with added regulatory responsibilities.

Response: We thank the commenters for their feedback. We note that a full discussion on the comments we received about the proposed change in waitlist status requirements and our responses are discussed later in this section.

Comment: Some commenters suggested that the proposed CMS waitlist notification requirement is largely duplicative of existing regulations and unnecessary. For example, a few commenters cited that such notifications are already mandated and audited under the existing conditions of participation (CoPs) for transplant hospitals, while a couple other commenters indicated that transplant hospitals already notify all waitlisted patients—regardless of payer—when their status changes from active to inactive, consistent with established departmental policies and standard operating procedures.

A few commenters expressed concern that imposing a new, separate requirement would create regulatory confusion, inefficiencies, and potential uncertainty for patients. They argued that a duplicative rule could lead to divergent communication methods based on a patient's payer source and would be an unnecessary overlay on systems that are already functioning effectively

and compassionately.

A commenter also conveyed that transplant hospitals often use their own internal systems for managing waitlists that are more nuanced than the binary active/inactive status proposed. For example, the commenter stated that transplant hospitals may use an "interim" status for temporary holds that do not affect a patient's official waitlist time but indicate their temporary unavailability, a level of detail the commenter believes that the proposed rule overlooks.

Another commenter stated that the underlying requirement to notify patients of status changes is already in place while highlighting that the only new requirement is the annual notification for patients who remain inactive over a year. Despite acknowledging that this requirement would add some administrative work for transplant hospitals, this commenter ultimately found this to be a reasonable and patient-centered addition that would enhance communication with this specific patient group.

Lastly, a commenter urged the agency to defer to OPTN policy regarding waitlist notifications, pointing out that the OPTN recently had its own public comment period on this issue and creating a separate CMS requirement would be redundant.

Response: We thank the commenters for their feedback. We acknowledge that certain transplant hospitals may already notify patients of waitlist status changes under existing CoPs, departmental policies, or standard operating procedures. However, as discussed in the 2025 Proposed Rule (90 FR 57618) and in this final rule, current regulations require notification when a patient is added to or removed from a waitlist but do not uniformly require notification when a patient's status changes from active to inactive. While some IOTA participants may already provide such notification as a matter of best practice, we believe the absence of a uniform, codified requirement contributes to variability in practice across transplant hospitals. Accordingly, we do not agree that this requirement is duplicative. Rather, it establishes a clear, standardized expectation across all IOTA participants to ensure consistent communication to applicable Medicare beneficiaries.

While some commenters expressed concern about regulatory confusion or divergent communication methods based on payer source, we respectfully disagree. The IOTA Model applies specifically to IOTA participants and IOTA waitlist patients who are Medicare beneficiaries attributed to the model. To the extent that IOTA participants already provide such notifications to all waitlisted patients, we do not believe that compliance with this provision would require substantial operational changes. Rather than creating confusion, we believe this requirement establishes a minimum transparency standard for Medicare beneficiaries participating in the model.

We acknowledge commenters' statements that transplant hospitals may use internal classifications, such as "interim" or temporary hold statuses, that are more nuanced than the binary active/inactive framework. We note that this provision does not restrict IOTA participants' internal processes. Rather, it requires notification when a change in status affects the patient's eligibility to receive kidney transplant organ offers. IOTA participants would be able to continue to use internal designations as appropriate, provided IOTA waitlist patients who are Medicare beneficiaries are informed when their ability to receive kidney transplant organ offers is impacted.

We also acknowledge the comment urging CMS to defer to OPTN policy regarding waitlist notifications. While we recognize the importance of coordination with OPTN and are aware of its related policy development efforts, CMS has independent authority to establish requirements within the IOTA Model to promote transparency, patient engagement, and beneficiary protections. We do not believe that establishing a model-specific requirement is redundant; rather, it ensures that IOTA waitlist beneficiaries who are Medicare beneficiaries receive consistent and timely information regarding their kidney transplant eligibility status.

With respect to the commenter who stated that, aside from the annual notification for patients who remain inactive for 365 consecutive days, many transplant hospitals already notify patients of status changes and that the annual requirement represents a reasonable, patient-

centered enhancement. We agree that the annual notification is an important additional safeguard. As discussed in the 2025 Proposed Rule (90 FR 57619), prolonged inactivity is associated with lower likelihood of transplantation and increased waitlist mortality, and knowledge deficits among transplant candidates are well documented. The annual notification requirement is intended to prevent patients from unknowingly remaining inactive for extended periods and to prompt re-engagement where appropriate. We continue to believe this provision appropriately balances patient awareness with administrative burden. Extended inactivity on a waitlist is associated with adverse outcomes, and periodic notification serves as an important safeguard against prolonged, unrecognized inactivation. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter supported CMS's rationale for not proposing to also require IOTA participants to notify IOTA waitlist patients who are Medicare beneficiaries when their waitlist status changes from inactive to active, agreeing that such a mandate could impose significant administrative burden, particularly on participants with limited resources, and could require investments in new systems and staff time that may detract from direct patient care. The commenter also agreed with CMS's concern that frequent status change notifications could create patient anxiety, foster unrealistic expectations regarding the immediacy of organ offers, and potentially overwhelm clinical teams, while standardized notification requirements may not adequately account for diverse patient literacy levels and communication needs. The commenter further asserted that these same concerns apply to the proposed requirements for notifications of changes from active to inactive status. In the commenter's view, uniform, boilerplate notifications alone are unlikely to meaningfully enhance transparency or patient empowerment. Instead, the commenter encouraged CMS to support transplant centers in continuing to provide real-time, personalized communication that offers patients clear, meaningful, and actionable information tailored to their individual circumstances.

Response: We thank the commenter for supporting our decision not to require IOTA

participants to notify IOTA waitlist patients who are Medicare beneficiaries when their status changes from inactive to active. We agree that mandating notification for every status change could impose additional administrative burden, particularly for participants with limited resources, and could require workflow modifications that may detract from direct patient care. We also acknowledge the commenter's concerns that frequent notifications could contribute to patient anxiety or unrealistic expectations regarding the immediacy of organ offers.

However, we respectfully disagree that these concerns warrant removal or modification of the requirement to notify patients when their status changes from active to inactive. A change from active to inactive status directly affects a patient's eligibility to receive organ offers and has immediate implications for access to transplantation. Ensuring that IOTA waitlist patients who are Medicare beneficiaries are informed when they become ineligible to receive offers is fundamental to transparency and patient engagement. Unlike reactivation, which restores eligibility, inactivation may go unrecognized by patients and could persist for extended periods without their knowledge. The notification requirement is intended to reduce the risk of prolonged, unrecognized inactivity and to provide patients with clear information about the reason for the change and steps necessary to regain active status.

We also do not agree that the change in waitlist status requirement necessitates rigid, boilerplate communication that would undermine individualized care. The provision establishes minimum content elements to promote consistency and accountability but does not prescribe a specific template or prohibit personalized, real-time discussions between transplant teams and patients. We expect that IOTA participants will continue to engage in individualized communication and view the required notification as a complement to, not a replacement for, patient-centered dialogue.

Accordingly, while we appreciate the commenter's perspective, we continue to believe that requiring notification when a patient's status changes from active to inactive appropriately balances transparency, patient protection, and administrative feasibility. Additionally, as noted

in comment responses previously in this section, we will be finalizing the proposed change in waitlist status requirements as proposed.

Comment: A few commenters urged CMS to expand the proposed change in waitlist status requirement to include notifications for both active to inactive and inactive to active waitlist status changes so that patients and their care teams receive timely, transparent updates that protect trust and ensure patients clearly understand their eligibility for organ offers. A commenter expressed agreement that patients should be notified when their waitlist status changes from active to inactive, recognizing that such a change directly affects a patient's eligibility to receive organ offers. The commenter supported ensuring that patients are informed of this status change to promote awareness and transparency. Additionally, the same commenter indicated no objection to also notifying patients when their status changes from inactive back to active and stated that they do not anticipate that providing such reactivation notifications would create a significant administrative burden.

Another commenter recommended that all status changes be formally documented and made visible in the patient's electronic health record (EHR) portal to promote transparency and accessibility. The commenter emphasized that patients should be clearly informed when their status changes, the effective date of the change, the reason for inactivation, and the specific steps necessary to regain active status. According to the commenter, because waitlist status directly affects a patient's eligibility to receive organ offers, failure to provide timely and clear notification may result in patients later discovering that they spent time inactive without their knowledge, which can cause significant distress and undermine trust in the transplant process.

Response: We thank the commenters for their thoughtful feedback and for emphasizing the importance of transparency in communicating changes in waitlist status. We agree that a change from active to inactive waitlist status directly affects a patient's eligibility to receive kidney transplant organ offers and that timely notification of such a change is essential to promoting patient awareness, engagement, and trust.

We carefully considered the commenters recommendations to also require notification when IOTA waitlist patients who are a Medicare beneficiary waitlist status changes from inactive to active. While we acknowledge that reactivation restores eligibility and that a commenter did not anticipate significant administrative burden associated with providing such notice, we continue to believe that limiting the regulatory requirement to active-to-inactive changes appropriately targets the most consequential transition. Inactivation results in a loss of eligibility to receive kidney transplant organ offers and may not always be readily apparent to patients, particularly if it occurs due to clinical or administrative factors that are not well understood. By contrast, reactivation typically occurs in the context of direct clinical engagement, resolution of previously identified issues, or completion of required testing, during which communication between the transplant team and the patient generally occurs. We remain concerned that requiring notification for every inactive-to-active waitlist status change could contribute to increased administrative complexity, particularly for IOTA participants with frequent status fluctuations, without commensurate benefit beyond existing clinical communication practices.

With respect to the commenter's recommendation that all status changes be formally documented and made visible in the patient's EHR portal, we note that, as described and finalized in this section, §§ 512.442(d)(1)(iii) and 512.442(d)(2) requires IOTA participants to provide notification electronically or by mail and to document in the patient's medical record a copy of the notification, the method of delivery, and the date sent. We believe these requirements promote accountability and traceability. Although we do not mandate a specific technological platform, such as an EHR portal, IOTA participants retain flexibility to leverage existing patient portal functionality or other electronic systems to meet the notification requirement, provided that all required elements are included and documentation standards are satisfied. We agree that notifications should clearly communicate the effective date of inactivation, the reason for the status change, and the steps necessary to regain active status, as

described and finalized at § 512.442(d)(1)(ii), and we believe these content requirements directly address the commenter's concerns about patients unknowingly spending extended periods in inactive status.

Accordingly, as mentioned in comment responses noted previously in this section, we will be finalizing the change in waitlist status requirements as proposed. However, we will take these insights and recommendations into consideration as we continue to consider ways to increase transparency and, if warranted, will propose a new or updated policy through future notice and comment rulemaking.

Comment: Numerous commenters expressed support for the proposed change in waitlist notification requirements and generally agreed that timely and transparent communication regarding changes from active to inactive status is critical to patient-centered care. They also encouraged CMS to include implementation approaches that ensure notifications are understandable, actionable, and integrated into patient-centered communication practices. For example, multiple commenters emphasized that understanding one's current waitlist status is among the most important pieces of information for transplant candidates, as it directly affects eligibility for organ offers and overall transplant opportunities. These commenters stated that formalizing notification requirements would promote greater consistency across transplant centers, where practices currently vary, and would help ensure that patients are not left unaware of status changes that could materially affect their care.

Many commenters specifically supported the proposal's requirement that notifications include not only the fact of the patient's status change, but also an explanation of why the patient was made inactive and clear instructions on the steps necessary to regain active status, highlighting the importance of including both the reason for inactivation and clear guidance on how to restore active status. These commenters noted that without this additional information, notifications risk becoming generic or overlooked communications that do not meaningfully empower patients. They underscored that providing specific, actionable guidance can help

patients understand what is required of them and reduce the likelihood that they unknowingly remain inactive for extended periods. Some of the same commenters further stressed that learning retrospectively that time was spent inactive can be distressing and erode patient trust, reinforcing the value of prompt and detailed notification within the proposed timeframe.

Some commenters indicated that notifying IOTA waitlist patients who are Medicare beneficiaries when their status on an IOTA participant's changes from active to inactive is consistent with existing regulatory expectations and standard practice and characterized the additional requirements—such as annual notifications for patients who remain inactive for an extended period—as reasonable and patient-centered despite some incremental administrative work. While some other commenters expressed that they did not anticipate significant burden associated with notifying IOTA waitlist patients who are Medicare beneficiaries when they return to active status on an IOTA participant's waitlist and had no objection to such communication, recognizing its value in keeping patients fully informed.

Response: We thank the commenters for their support of the proposed change in waitlist status notification requirements and for emphasizing the importance of timely and transparent communication when a patient's waitlist status changes from active to inactive. We agree that understanding one's waitlist status is a critical component of patient-centered care, as inactive status directly affects a transplant candidate's eligibility to receive kidney transplant organ offers. As stated in this section and in the 2025 Proposed Rule at 90 FR 57619, numerous research studies have demonstrated that kidney transplant waitlist patients frequently experience confusion regarding the transplant evaluation and waitlisting process, including whether they are active on the waiting list and therefore eligible to receive organ offers. We believe that establishing a standardized requirement for IOTA participants to notify IOTA waitlist patients who are Medicare beneficiaries when their waitlist status changes will promote consistency across transplant hospitals and help ensure that patients are promptly informed of changes that may materially affect their opportunity for transplantation.

We further appreciate commenters' support for the requirement that the notification include not only the fact that a status change has occurred but also additional information explaining the reason for the change and the steps necessary to regain active status. As described in this section of this final rule and in the 2025 Proposed Rule at 90 FR 57620, the notification must include the most recent date on which the IOTA waitlist patient who is a Medicare beneficiary became inactive, the reason for the change in waitlist status, a statement explaining that the patient cannot receive organ offers while inactive, information regarding how the patient may become active again on the waitlist, and contact information for the transplant hospital. We agree with commenters that inclusion of this information is essential to ensuring that notifications are both meaningful and actionable. We believe that the provision of clear explanations and guidance can assist IOTA waitlist patients who are Medicare beneficiaries in better understanding their status and reduce the likelihood that they remain inactive for extended periods due to misunderstanding or lack of awareness.

Commenters additionally noted that formalizing these requirements may enhance patient trust by reducing the possibility that patients subsequently discover they spent time inactive without their knowledge. We agree that prompt and detailed notification can serve to reinforce transparency and engagement in the transplant process. As such, we believe that the notification requirements at § 512.442(d)(1)(ii), together with the delivery and documentation provisions, as described and finalized in § 512.442(d) of this final rule, appropriately support patient awareness and understanding of transplant eligibility status.

Finally, we acknowledge commenters' observations that certain IOTA participants may already provide similar notifications as part of existing practice and that the additional requirements may involve some incremental administrative effort, such as annual notifications for patients who remain inactive. Notwithstanding these considerations, we believe these provisions represent a reasonable and patient-centered approach to ensuring that IOTA waitlist patients who are Medicare beneficiaries remain informed regarding their eligibility for kidney

transplant organ offers and the steps necessary to regain active status. For these reasons, we are finalizing the proposed change in waitlist status notification requirements at § 512.442(d)(1)(ii) without modification.

Comment: Several commenters expressed support for improving patient awareness of waitlist status changes but expressed concern that the proposed change in waitlist status notification requirements could create significant administrative burden, patient confusion, and potential mistrust due to the complex, dynamic nature of transplant care. A commenter expressed support for the concept of sharing information with patients regarding transitions from active to inactive waitlist status, noting that such transparency is consistent with broader efforts to provide patients with meaningful information about their own care. This commenter affirmed the value of ensuring patients receive this information and recognized its importance from the patient perspective. However, the commenter raised concerns that requiring IOTA participants to provide each patient with a detailed explanation of how to regain active waitlist status could impose additional administrative burden, create time pressures, and result in unreimbursed costs. The same commenter suggested that, similar to policies involving the communication of organ offer declines, this effort may warrant the development of a billing code to account for the time and complexity involved in conveying, either in writing or verbally, the individualized steps necessary for a patient to become active on the waitlist again.

Another commenter expressed support for the proposal's intent to enhance communication and care coordination by requiring notification to IOTA waitlisted Medicare beneficiaries when their status changes from active to inactive, including the reason for inactivation, steps for reactivation, and concurrent notification to the dialysis facility and managing clinician or nephrologist within 10 business days. However, the commenter raised concerns regarding operational and administrative implications. The commenter noted that inactivation is often temporary or multifactorial, such as when related to insurance authorization issues or pending diagnostic test results, and stated that requiring detailed, step-by-step

reactivation instructions in these situations could impose unnecessary administrative burden and potentially increase patient anxiety or confusion. The commenter also requested clarification regarding the annual notification requirement, observing that a strict 365-day timeframe could create operational challenges, particularly because transplant hospital communications are generally limited to business days and do not typically occur on weekends or holidays. The commenter sought additional guidance on operational expectations, documentation requirements, and how the proposed requirements would align with existing notification workflows to minimize duplicative or conflicting processes.

Lastly, a commenter agreed with CMS' reasoning for not proposing to require IOTA participants to also notify their IOTA waitlist patients who are Medicare beneficiaries whenever their status changes from inactive to active in addition to whenever their waitlist status changes from active to inactive. The commenter stated that these concerns also apply to the proposed waitlist status notification requirements more broadly. The commenter believed that uniform, boilerplate notifications—whether for changes from active to inactive status or vice versa—are unlikely on their own to meaningfully enhance transparency or patient empowerment. Instead, the commenter recommended that transplant hospitals be supported in continuing to provide real-time, individualized communication that offers patients clear, relevant, and actionable information tailored to their specific circumstances.

Response: We thank the commenters for their support of improving patient awareness of waitlist status changes and for recognizing the importance of transparency when an IOTA waitlist patient who is a Medicare beneficiary transitions from active to inactive status. We also acknowledge these concerns and understand that transplant candidacy and waitlist status can fluctuate due to various clinical or administrative factors.

To address the comment we received requesting clarification regarding the operational expectations, documentation requirements, and how the proposed change in waitlist status annual notification requirement requirements would align with existing notification workflows to

minimize duplicative or conflicting processes we clarify that days, as defined at § 512.402 means calendar days unless otherwise specified by CMS. We also clarify that the change in waitlist status documentation requirements, as described and finalized in § 512.442(d)(2) of this final rule is applicable to the change in waitlist status notification requirements as described and finalized in § 512.442(d)(1)(iii) of this final rule.

As mentioned in comment responses noted previously, we continue to believe that the change in waitlist status notification requirements at § 512.442(d)(1)(ii) appropriately balance transparency, patient protection, and operational feasibility and are finalizing these provisions without modification. However, we will take these insights and recommendations into consideration as we continue to assess our change in waitlist status provision and, if warranted, will propose a new or updated policy through future notice and comment rulemaking.

Comment: Several commenters discussed the importance of ensuring consistent, transparent, and nationally aligned approaches to patient communication within the transplant system. Some of these commenters supported the intention of improving communication by notifying patients of changes in their waitlist status, such as moving from active to inactive. However, they overwhelmingly argued that such a requirement should be established uniformly across all transplant programs through the OPTN policy process, rather than being a requirement unique to the IOTA Model. These commenters suggested that applying this standard only to IOTA participants could create inconsistent standards within the transplant system and potentially disadvantage patients at kidney transplant hospitals not participating in the model.

A few commenters noted that the OPTN has already been actively developing a policy on this same issue, including a recent public comment period. They urged CMS to defer to the OPTN's process to avoid regulatory confusion and unnecessary duplication of effort for transplant programs. These commenters expressed concern that creating a separate CMS requirement would be redundant and impose an additional administrative burden on IOTA participants that non-participants would not have to bear.

A few commenters also raised concerns about timing and administrative burden. These commenters noted uncertainty regarding whether and when the OPTN proposal would be finalized and expressed concern that, if CMS were to finalize IOTA-specific requirements and OPTN subsequently adopted different requirements, IOTA participants could be subject to duplicative or conflicting notification regimes. They stated that preparing for multiple potential standards would increase administrative burden without corresponding benefits and urged CMS to avoid creating parallel regulatory structures.

Response: We thank the commenters for their thoughtful feedback regarding the importance of consistent, transparent, and nationally aligned approaches to patient communication within the transplant system. We appreciate commenters' recognition that notifying patients when their waitlist status changes, particularly when a change from active to inactive status affects their eligibility to receive organ offers, can meaningfully improve patient awareness and engagement in the transplant process. We also acknowledge commenters' concerns that establishing this requirement within the IOTA Model could create differences in communication standards between transplant hospitals participating in the model and those that are not.

While we recognize the value of nationally consistent policies, we do not agree that the existence of ongoing or potential policy development through the OPTN precludes CMS from establishing model-specific requirements where appropriate to advance the goals of the Innovation Center model. The IOTA Model is designed to test approaches that improve transparency, patient engagement, and access to transplantation for Medicare beneficiaries. As part of this effort, we believe that requiring IOTA participants to notify IOTA waitlist patients who are Medicare beneficiaries when their waitlist status changes from active to inactive—including providing key information about the reason for inactivation, the implications for transplant eligibility, and steps that may support reactivation—represents an important patient-centered safeguard. Establishing these minimum communication standards within the model

allows CMS to evaluate whether improved transparency and patient awareness contribute to better engagement and progress toward transplantation among IOTA waitlist patients who are Medicare beneficiaries.

We acknowledge commenters' statements that the OPTN has recently sought public comment on a related policy addressing notification of waitlist status changes and that stakeholders are interested in avoiding redundant or conflicting requirements. We appreciate these perspectives and note that CMS works closely with other components of HRSA, which oversees the OPTN contract, to promote alignment where appropriate. However, the OPTN policy process and CMS rulemaking operate under distinct statutory authorities and serve different policy purposes. The OPTN establishes national organ allocation and transplant system policies applicable to all transplant programs, while CMS establishes requirements governing Medicare participation, payment models, and beneficiary protections. As such, CMS may adopt model-specific requirements that support the objectives of the Innovation Center, even where related policies are being considered through the OPTN.

We also understand commenters' concerns regarding timing and the potential for administrative burden if IOTA participants were required to prepare for multiple notification standards. We note, however, that the requirements finalized in this final rule are narrowly tailored and focused on ensuring that IOTA waitlist patients who are Medicare beneficiaries are informed when their eligibility to receive kidney transplant organ offers is affected. As indicated by comments we received on this provision, some transplant hospitals already maintain processes to communicate waitlist status changes as part of routine clinical practice or institutional policy. Accordingly, we expect that IOTA participants will be able to integrate these requirements into existing patient communication and documentation workflows without substantial additional burden. Moreover, the regulation provides flexibility regarding the specific format and operational implementation of the notification, allowing participants to leverage existing communication systems such as electronic health records, patient portals, or

mailed correspondence.

Finally, we recognize the importance of maintaining alignment across federal transplant oversight activities where feasible and will continue to monitor developments in OPTN policy in this area. Should the OPTN adopt related requirements applicable across the transplant system, CMS will evaluate those policies and consider whether any adjustments to the IOTA Model requirements may be appropriate in future rulemaking to ensure clarity and minimize unnecessary duplication. At this time, however, we continue to believe that establishing the change in waitlist status notification requirement within the IOTA Model is appropriate to advance transparency and beneficiary awareness within the model. We reiterate that, as mentioned in comment responses noted previously in this section, we are finalizing the proposed change in waitlist status notification content requirements at § 512.442(d)(1)(ii) without modification. However, we will take these insights and recommendations into consideration as we continue to assess our change in waitlist status provision and, if warranted, will propose a new or updated policy through future notice and comment rulemaking.

Comment: A few commenters cited the differences between the IOTA Model and OPTN proposals for notifying patients of changes to their waitlist status, ultimately advocating for a unified, comprehensive, and patient-centered communication process to ensure the critical information is effectively received and understood. For example, a commenter expressed strong support for the change in waitlist status policy proposed in the IOTA Model, which, compared to the similar policy proposed by the OPTN, includes additional components that are critically important to ensuring the policy's effectiveness. Specifically, the commenter highlighted the value of requiring that notifications to patients include clear information on how the patient may become active on the transplant waitlist again. The commenter noted that providing actionable, easy-to-understand instructions is essential to helping patients understand next steps and avoid prolonged inactivity due to confusion or lack of awareness. Additionally, the commenter underscored the importance of requiring concurrent notification to the patient's dialysis facility

and nephrologist, explaining that engaging these providers creates a stronger support system to help patients navigate the reactivation process. Without these added requirements, the commenter cautioned that the notification could become just another message delivered through a patient portal that may go unread or unaddressed, thereby limiting the policy's intended impact on improving patient awareness and access to transplantation.

Another commenter expressed general support for the proposal but raised concerns about potential misalignment between the proposed IOTA Model requirements and a recently issued OPTN proposal addressing notification to waitlisted patients of a change in status from "active" to "inactive." The commenter noted that the OPTN proposal would apply broadly to all waitlisted patients, regardless of IOTA beneficiary status, and that OPTN is currently seeking stakeholder input on appropriate methods of communication, such as letters, phone calls, or electronic health record notifications, and the circumstances under which each method would be sufficient. The commenter further observed that the additional requirements proposed in the IOTA Model—specifically, communicating and documenting the reason for a status change and explaining how a patient may regain active status—are not contemplated under the current OPTN proposal revision. To avoid potential inconsistencies or duplicative requirements for IOTA participants, the commenter encouraged CMS to coordinate with HHS and OPTN to align policies where possible and to build upon the existing OPTN proposal. To prevent inconsistencies or duplicative obligations for IOTA participants, the commenter suggested that CMS coordinate with HHS and OPTN to build upon the existing OPTN proposal and to consider broader notification standards that could apply uniformly to all waitlisted candidates. Although supportive of efforts to enhance transparency, the commenter cautioned that discordant policy requirements between CMS and OPTN could create confusion and administrative burden, and stated that minimizing such discrepancies where possible would be preferable.

Response: We thank the commenters for their thoughtful feedback and for emphasizing the importance of clear, patient-centered communication when a transplant candidate's waitlist

status changes. We appreciate commenters' support for aspects of the proposed IOTA Model policy and their recognition that including actionable information, such as how a patient may regain active waitlist status, can help ensure that notifications are meaningful and support patient engagement. As described in the 2025 Proposed Rule (90 FR 57620) and in the preamble of this final rule, we proposed at § 512.442(d)(1)(ii) that notifications to IOTA waitlist patients who are Medicare beneficiaries include specific content elements, including the most recent date of inactivation, the reason for the status change, a statement explaining that inactive patients cannot receive organ offers, and information on how the patient may become active again on the transplant waitlist. We believe these elements help ensure that IOTA waitlist patients who are Medicare beneficiaries receive clear, actionable information necessary to understand their eligibility and next steps toward reactivation.

We also agree with commenters that engaging a patient's broader care team can strengthen communication and support reactivation. As described and finalized in this section of this final rule, the provision at § 512.442(d)(3) requires IOTA participants to notify the dialysis facility and managing clinician or nephrologist (for ESRD patients), or the referring provider (for non-ESRD patients), when a change in waitlist status occurs. We believe this coordinated approach can help ensure that IOTA waitlist patients who are Medicare beneficiaries receive consistent information and support from clinicians involved in their care.

Commenters also noted potential differences between the proposed IOTA Model change in waitlist status requirements and a related proposal under consideration by the OPTN[108]. For clarity, we summarize key elements of the two proposals in Table 11.

TABLE 11: COMPARISON – CHANGE IN WAITLIST STATUS REQUIREMENTS PROPOSED UNDER OPTN POLICY AND THE IOTA MODEL

Policy Element	OPTN	IOTA Model
Applicability	Applies to all transplant programs participating in the OPTN	Applies only to kidney transplant hospitals participating in the IOTA Model
Patients Covered	All transplant candidates on the OPTN waiting list	IOTA waitlist patients who are Medicare beneficiaries
Status Changes Covered	Notification required when a candidate's status	Notification required when a status change affects

108 Require Patient Notification for Waitlist Status Changes | HRSA. (2025, October 29). Hrsa.gov. *https://www.hrsa.gov/optn/policies-bylaws/public-comment/require-patient-notification-for-waitlist-status-changes*

Policy Element	OPTN	IOTA Model
	changes from active to inactive or inactive to active	ability to receive organ offers, that is active to inactive (CMS sought comment on also requiring inactive to active notifications)
Timing of Notification	Must notify the candidate within 10 business days of the waitlist status change	Must notify the patient within 10 days of the status change
Notification Method	Proposed as written notification, but OPTN is considering allowing phone or conversation if documented in the patient record	Must provide notification electronically or by mail
Required Information in Notification	Inform the candidate that their waitlist status has changed (active ↔ inactive)	Must include: • Date the patient became inactive • Reason for status change • Explanation that the patient cannot receive organ offers while inactive • Instructions on how to become active again • Contact information for questions
Documentation Requirements	Programs must document the communication in the candidate's record	IOTA participants must retain a copy of the notification and record the delivery method and date in the IOTA waitlist patient who is a Medicare beneficiary's medical record.
Additional Provider Notification	Not specified in the proposal	Requires notification of dialysis facility and managing clinician/nephrologist (for ESRD patients) or the referring provider
Ongoing Notifications if Inactive	No recurring notification requirement specified	Requires annual notification if the patient remains inactive for 365 consecutive days
Primary Policy Objective	Improve patient awareness and transparency regarding waitlist status	Improve transparency, patient engagement, and understanding of transplant eligibility status

We acknowledge commenters' concerns regarding potential differences between CMS and OPTN policies. CMS and HRSA coordinate closely on transplant system oversight, and we will continue to monitor developments in OPTN policy. However, CMS has independent authority to establish requirements within Innovation Center models to test approaches that improve transparency, care coordination, and patient engagement for Medicare beneficiaries. The additional content elements included in the IOTA Model are intended to ensure that IOTA waitlist patients who are Medicare beneficiaries receive clear, actionable information when their eligibility to receive kidney transplant organ offers is affected.

We appreciate commenters' recommendations for alignment across federal transplant oversight activities and recognize the importance of coordination where feasible. CMS will continue to coordinate with HHS and OPTN, as appropriate, as related policies evolve. At this time, however, we continue to believe that the notification content requirements finalized in the IOTA Model appropriately support the model's goals of improving patient awareness and engagement by ensuring that IOTA waitlist patients who are Medicare beneficiaries receive clear, actionable information when their waitlist status changes from active to inactive. For these

reasons, we are finalizing the proposed change in waitlist status notification content requirements at § 512.442(d)(1)(ii) without modification.

Comment: Many commenters opposed the proposed waitlist status notification requirements, citing concerns about operational burden, duplication of existing requirements, and the potential for patient confusion. For example, a few of these commenters stated that transplant centers already maintain established processes for notifying patients of changes in waitlist status, including active-to-inactive transitions, or that these processes are governed and audited under existing CMS Transplant CoPs. In particular, a commenter argued that layering additional IOTA Model-specific notification requirements on top of current obligations would be duplicative and unnecessary, particularly where transplant programs already notify all waitlisted patients, regardless of payer, of status changes as part of standard operating procedures.

Several commenters asserted that the proposed requirements would impose substantial administrative and operational burdens on transplant programs, especially those managing large waitlists or experiencing frequent status changes. They stated that kidney transplant hospitals may lack the infrastructure and staffing necessary to comply with detailed notification, documentation, and timeline requirements, and that implementation could require significant workflow redesign and new expenditures. These same commenters expressed concern that compliance efforts could divert resources from direct patient care, potentially delay transplant services, and overwhelm clinical teams with regulatory tasks.

Response: We thank the commenters for their feedback and acknowledge the concerns raised regarding operational burden, potential duplication, and patient confusion; however, we respectfully disagree that the proposed change in waitlist status notification requirements is duplicative or unnecessary. We recognize that some IOTA participants may already have established processes for notifying patients of changes in waitlist status. In the 2025 Proposed Rule (90 FR 57618) we acknowledged that 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)). However, as we stated the 2025 Proposed Rule (90 FR 57618), 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. Furthermore, while current CoPs for transplant hospitals address certain notification obligations, they do not explicitly require standardized notification to patients when their waitlist status changes from active to inactive, nor do they require inclusion of specific content elements such as the most recent date of inactivation, the reason for the change, the effect on eligibility to receive organ offers, and clear information on how to regain active status. As such, we believe that the proposed change in waitlist status notification provision at § 512.442(d)(1)(ii) establishes consistent minimum content standards for IOTA participants to ensure that IOTA waitlist patients who are Medicare beneficiaries receive complete, actionable information when their eligibility to receive kidney transplant organ offers is affected.

We also recognize the concerns regarding administrative and operational burden, particularly for IOTA participants with large waitlists or frequent status changes. However, the proposed change in waitlist status requirement is narrowly tailored to apply to IOTA waitlist patients who are Medicare beneficiaries when their waitlist status changes from active to inactive and to require inclusion of specific information that we believe is essential to patient understanding and engagement. We expect that many IOTA participants will be able to integrate these requirements into existing communication workflows and documentation systems, including EHRs and established patient notification processes. We also note that the proposed requirement does not prescribe a specific format or delivery mechanism beyond what is already outlined in the broader provision, as described and finalized in § 512.442(d)(1)(iii) of this final rule, thereby preserving flexibility for IOTA participants to operationalize the requirement in a manner consistent with their infrastructure and patient population.

Additionally, we do not believe that compliance with these requirements will divert resources from direct patient care or delay transplant services. Rather, we believe that clear and timely communication regarding inactive status supports patient engagement, may reduce prolonged unrecognized inactivation, and promotes more efficient progression toward reactivation where appropriate. Because inactive status directly affects a patient's eligibility to receive organ offers, ensuring that patients are informed of the reason for inactivation and the steps necessary to regain eligibility provides transparent and actionable information that enhances patient-centered care, promotes accountability, reduces confusion, and may help mitigate inefficiencies associated with delays in reactivation. For these reasons, we are finalizing our proposal without modification. However, we will take these insights and recommendations into consideration as we continue to assess our change in waitlist status provision and, if warranted, will propose a new or updated policy through future notice and comment rulemaking,

Comment: A commenter supported CMS's proposal to require IOTA participants to notify IOTA waitlist patients who are Medicare beneficiaries on its transplant waitlist within 10 days of a change in status from active to inactive, including providing the reason for the change and the steps necessary to regain active status. The commenter further recommended that this requirement be applied uniformly to all waitlisted patients, rather than limited to IOTA waitlist patients who are Medicare beneficiaries. The commenter stated that timely notification of waitlist status changes is essential to promoting patient understanding, engagement, and continuity of care, and characterized such communication as a foundational element of a patient-centered transparency standard.

Response: We would like to thank the commenter for their support. We also appreciate the commenter's recommendation that this requirement apply to all waitlisted patients. However, the IOTA Model is an Innovation Center model operating under the authority of section 1115A of the Act and is designed to test approaches that improve transparency, care

coordination, and access to transplantation for Medicare beneficiaries. Accordingly, CMS's regulatory authority within the model is limited to establishing requirements for IOTA participants with respect to IOTA waitlist patients who are Medicare beneficiaries. While this provision applies specifically to that population, nothing in this final rule precludes IOTA participants from providing similar notifications to all of its waitlisted patients as part of their standard patient communication practices. Therefore, as mentioned in comment responses noted previously in this section, we are finalizing our proposal without modification.

Comment: A few commenters supported CMS' efforts to improve patient communication and care coordination but urged CMS to not finalize the proposed change in waitlist status delivery method and timeline requirements, citing significant operational concerns. The commenters stated that many transplant programs lack the administrative infrastructure and staffing necessary to manage communications with potentially large numbers of active waitlisted candidates and indicated that implementing the proposed requirements would likely require substantial new costs and workflow redesign. They further cautioned that, rather than improving clarity, the requirements could create confusion for patients regarding their status, options, and expected outcomes. They also emphasized that the proposal lacks sufficient detail regarding how communications should be conducted, what would constitute acceptable documentation, and how compliance would be evaluated. Absent clearer guidance, the same commenters warned that the requirements could overwhelm transplant programs, divert resources away from direct clinical care, and potentially delay transplant services.

Response: We thank the commenters for their support of the goal of improving patient communication and care coordination and for sharing concerns regarding the operational impact of the proposed delivery method and timeline requirements. We recognize that transplant hospitals vary in size, resources, and administrative capacity, and we carefully considered these factors in developing the requirements at § 512.442(d)(1)(iii).

However, we disagree that the proposed delivery method and timeline requirements are

likely to impose significant new infrastructure demands or necessitate substantial workflow redesign. The provision, as proposed, requires IOTA participants to furnish the change in waitlist status notification to IOTA waitlist patients who are Medicare beneficiaries electronically or by mail within 10 days of the change in waitlist status from active to inactive and annually thereafter for as long as the Medicare beneficiary remains inactive (that is, 365 consecutive days). These parameters are intended to promote timely, consistent communication and accountability; however, they do not prescribe a specific format, staffing model, or communication platform. IOTA participants retain the discretion to integrate these requirements into their existing communication processes, including EHR systems, patient portals, or established mail-based notification procedures. Furthermore, we believe that the majority of IOTA participants already maintain mechanisms to communicate changes in waitlist status and to document such communications within the medical record. As such, we do not anticipate that these requirements will necessitate the development of extensive new infrastructure.

We also do not agree that the requirements, as proposed, will create confusion for patients. Providing a notification when there is a change in waitlist status from active to inactive within a defined timeframe ensures that patients are promptly informed when their eligibility to receive organ offers is affected and reinforces understanding through periodic communication during prolonged inactivity. As noted in comment responses earlier in this section, this structured approach is intended to enhance clarity, reduce the likelihood of prolonged unrecognized inactivity, and support informed decision-making. We also note that the regulation establishes clear expectations regarding the timing and method of notification and documentation but intentionally allows flexibility in how IOTA participants operationalize these requirements to accommodate diverse workflows and patient communication needs.

Lastly, with respect to compliance expectations, we note that while the proposed change in waitlist status documentation requirements, as described in this section, specifies the required elements of notification and documentation, it does not impose overly prescriptive standards

beyond those elements. This approach is intended to provide clarity while minimizing administrative burden. We anticipate that IOTA participants will implement these requirements in a manner consistent with existing compliance and documentation practices. By promoting timely and well-documented communication, the policy is intended to support, rather than detract from, direct patient care and may reduce downstream administrative burden associated with resolving misunderstandings regarding waitlist status. For these reasons, we are finalizing the proposed change in waitlist status delivery method and timeline requirements at § 512.442(d)(1)(iii)) without modification.

Comment: A commenter stated that CMS' proposal to require IOTA participants to provide this notification to the IOTA waitlist patient who is a Medicare beneficiary annually, thereafter, for as long as the Medicare beneficiary remains inactive (that is; 365 consecutive days) is unnecessary and believed that it would add administrative burden and contribute towards increased healthcare cost.

Response: We thank the commenter for their feedback and for raising concerns regarding the potential administrative burden and cost associated with the proposed annual notification requirement. We acknowledge that this proposed provision would require IOTA participants to maintain processes to track inactive status and provide ongoing communication to affected patients on an annual basis. However, we disagree that the annual notification requirement is unnecessary. Extended periods of inactive status may not be readily apparent to patients, particularly when inactivity results from clinical, logistical, or administrative factors that evolve over time. In the absence of periodic communication, patients may remain inactive on a transplant hospital's waitlist for prolonged periods without fully understanding their status or the steps necessary to regain eligibility to receive organ offers.

While the proposed provision requiring IOTA participants provide the change in waitlist status notification within 10 days of the IOTA waitlist patient who is a Medicare beneficiary's change in waitlist status ensures that these patients are informed at the time their status initially

changes, the annual notification serves a distinct purpose: it reinforces ongoing transparency and patient engagement during periods of prolonged inactivity. Furthermore, as discussed in the 2025 Proposed Rule (90 FR 57618 through 90 FR 57619) and in the preamble of this section, patients may remain inactive for extended durations due to unresolved medical, testing, or administrative issues, and without periodic communication, they may presume they are still eligible to receive transplant offers. Requiring IOTA participants to notify IOTA waitlist patients who are Medicare beneficiaries every 365 days ensures that these patients are reminded of their status, understand the reasons for their inactivity, and are afforded an opportunity to work with their care team to address barriers to reactivation. Accordingly, the annual notification requirement is intended to serve as a patient-centered safeguard that reinforces transparency, promotes patient engagement, and helps prevent prolonged unintended inactivity.

We believe that providing this information on an annual basis strikes an appropriate balance between patient benefit and administrative feasibility. We further note that the requirement is limited in scope, as it applies only to IOTA waitlist patients who are Medicare beneficiaries and who remain inactive for 365 consecutive days, and it does not prescribe a specific format or communication platform beyond requiring that notification be provided electronically or by mail. We also believe that IOTA participants may integrate this requirement into existing patient communication and documentation systems, which should serve to mitigate additional burden. Moreover, ensuring that patients remain informed of their inactive status on the IOTA participant's waitlist may reduce downstream administrative work associated with re-engaging patients who were previously unaware of their inactivity. Therefore, as mentioned in comment responses previously in this section, we are finalizing the proposed change in waitlist status delivery method and timeline requirements at § 512.442(d)(1)(iii)) without modification.

Comment: Multiple commenters supported the goal of improving transparency regarding changes in waitlist status but recommended a centralized, technology-driven approach to implementation and delivery of these notifications in order to balance patient engagement with

operational feasibility. A commenter recommended development of a centralized platform that would allow prospective patients and donors to access hospital-specific information about transplant programs, such as evaluation criteria, compare transplant hospitals, and review individualized information about their own care, including organ offer declines and waitlist status. The commenter stated that such a platform would advance patient-centered transparency by improving the navigability of the transplant system and enabling patients to make more informed decisions. In addition, the commenter noted that centralizing this information would help minimize administrative burden on transplant hospitals, which might otherwise need to allocate significant resources to compiling and distributing this information, thereby allowing those resources to remain focused on direct patient care.

A few commenters recommended that waitlist status information be made available through a HRSA- or OPTN-developed patient-facing platform that would allow patients to log in and review their waitlist status in real-time, rather than relying solely on notifications from transplant centers. In particular, a commenter noted that several proposed transparency requirements, including notifications of organ offer declines and waitlist status changes, rely on accurate identification of CMS-attributed beneficiaries and urged CMS to avoid requiring hospitals to duplicate information already maintained in OPTN systems. The commenter recommended that CMS securely transmit relevant beneficiary-attribution lists to the OPTN to enable automated generation of standardized, patient-specific reports for Medicare beneficiaries. According to the commenter, this approach would improve accuracy, reduce manual reconciliation by hospitals, standardize notification formats, and significantly lessen administrative burden. The commenter suggested that reports could be distributed directly by CMS or made available through a secure OPTN-developed patient portal and encouraged collaboration among CMS, HRSA, and the OPTN to leverage existing data expertise. The commenter stated that centralized reporting and distribution would promote consistency, reduce variation, and support the goals of the model.

Another commenter supported the goal of notifying patients about changes in their waitlist status but raised concerns about how best to implement such notifications without overwhelming patients or transplant centers. The commenter stated that requiring kidney transplant hospitals to issue notifications each time a waitlist status changes may be unsustainable, particularly for high-volume programs with large waitlists, and could create operational strain. To address these concerns, the commenter recommended development of a secure online portal through which patients could access their waitlist information at any time. Specifically, the commenter suggested that patients be able to view their current active or inactive status, the length of time they have been active, the number of organ offers received, and the OPTN refusal codes associated with declined offers. The commenter also proposed that patients be allowed to designate their preferred method of communication, such as phone, text, or email, and that notifications of status changes be delivered automatically through those preferred channels, potentially by a centralized contractor. The commenter further suggested that the new OPTN vendor be tasked with developing and implementing such a solution to ensure a sustainable, system-wide approach. The commenter maintained that this approach would promote transparency and patient engagement while reducing administrative burden on transplant hospitals.

Response: We thank the commenters for their support of the goal of improving transparency regarding changes in waitlist status and for their thoughtful recommendations regarding centralized, technology-driven approaches to notification delivery. We agree that enhancing patient access to information and reducing unnecessary administrative burden are important objectives and we recognize the potential benefits of centralized platforms, including enhanced patient access to information, improved consistency, and reduced administrative burden on transplant hospitals. We also acknowledge the value of leveraging existing data systems, such as those maintained by the OPTN, and the importance of coordination across CMS, HRSA, and OPTN to support patient-centered transparency. However, as mentioned in

comment responses noted previously in this section, we are finalizing the change in waitlist status delivery method and timeline requirements at § 512.442(d)(1)(iii) without modification.

As discussed in this section, the purpose of this provision is to establish clear, timely and direct communication requirements that ensure IOTA waitlist patients who are Medicare beneficiaries are informed when their eligibility to receive kidney transplant organ offers is affected. We believe that direct notification from the IOTA participant is critical to ensuring accountability, clarity, and appropriate clinical context, and cannot be fully replaced by passive access to information through a centralized portal.

We recognize that the development of centralized, patient-facing platforms involves complex considerations, including data governance, privacy protections, interoperability, and coordination across federal agencies and the OPTN. While such approaches may present future opportunities to enhance transparency and streamline reporting, they are beyond the scope of this rulemaking. The provision is intended to be implemented using existing communication methods and systems currently in place at transplant programs, thereby minimizing the need for new infrastructure while ensuring that Medicare beneficiaries are promptly informed of changes to their waitlist status that affect their ability to receive kidney transplant organ offers.

Additionally, we note that the requirements do not prohibit the use of centralized tools or patient portals where available. IOTA participants may continue to use or adopt such technologies to supplement required notifications, provide additional information, or offer patients alternative methods of engagement. However, we believe that requiring IOTA participants to provide timely notification remains the most reliable and feasible approach to ensuring IOTA waitlist patients who are Medicare beneficiaries receive critical information about their status. Centralized solutions may complement, but not replace, direct communication from IOTA participants, which remains essential for individualized care coordination.

Comment: A commenter addressed CMS's proposal to require notification to the patient, nephrologist, and dialysis center within 10 days of a change in waitlist status and emphasized the

importance of implementing these transparency requirements in a patient-centered manner. To support effective implementation, the commenter recommended that CMS convene multidisciplinary work groups that include patients, living donors, transplant centers, patient advocacy organizations, donor families, and researchers. The commenter suggested that these stakeholders collaborate to co-develop education standards and standardized written notification formats to promote clarity, consistency, and meaningful patient engagement across the transplant system.

Response: We thank the commenter for their support of the transparency goals of the policy and for emphasizing the importance of patient-centered implementation. We also appreciate the commenter's recommendation that CMS convene multidisciplinary work groups, including patients, living donors, transplant centers, advocacy organizations, donor families, and researchers, to support implementation and develop education standards and standardized written notification formats. We agree that input from a broad range of stakeholders can provide valuable perspectives on effective communication practices and patient education within the transplant system. While this final rule establishes minimum regulatory requirements regarding the timing and method of notification, it does not prescribe a specific template or standardized format for the change in waitlist status notification. We note that this approach is intended to provide IOTA participants with flexibility to tailor communications to their patient populations, existing communication systems, and clinical workflows while still ensuring that required information is conveyed clearly and consistently.

Although we are not establishing stakeholder work groups or standardized notification templates through this rulemaking, we recognize the potential value of continued collaboration with patients, providers, and other transplant system stakeholders to inform best practices for patient-centered communication. CMS will continue to engage with stakeholders, including through existing forums and future policy development activities, to support effective implementation of transparency provisions within the IOTA Model. For the reasons discussed in

this section of this final rule, we are finalizing the proposed change in waitlist status delivery method and timeline requirements at § 512.442(d)(1)(iii) without modification.

Comment: A commenter believed that the OPTN proposal and the proposed change in waitlist status notification requirements in the IOTA Model differ in several important respects. The commenter noted that, under the IOTA Model, change in waitlist status notifications would be more comprehensive in content and could be delivered through a broad range of communication methods, but would only be required when a candidate becomes inactive, not when the candidate is reactivated. In contrast, the OPTN proposal would require notification via U.S. mail and would apply both when a candidate becomes inactive and when the candidate becomes active again. The commenter explained that their recommended approach would combine elements of both proposals but would differ in a significant way by emphasizing direct, patient-centered communication. Specifically, the commenter recommended that any change in waitlist status be communicated through a discussion between the candidate and a member of the transplant team, with the interaction documented in the candidate's medical record. The commenter stated that this approach would be more effective than written notification alone, regardless of delivery method, provided that the candidate can be reached in a timely manner, and would better support meaningful patient understanding and engagement.

Response: We thank the commenter for their thoughtful comparison of the IOTA Model proposal and the OPTN proposal and for emphasizing the importance of direct, patient-centered communication when waitlist status changes occur. As discussed previously in comment responses in this section, we acknowledge that the IOTA Model and OPTN proposals differ in scope, delivery methods, and the status changes that trigger notification. We also agree that discussions between transplant team members and transplant candidates are an important component of patient-centered care and can enhance patient understanding and engagement. However, as mentioned in comment responses noted previously in this section, we are finalizing the change in waitlist status delivery method and timeline requirements at § 512.442(d)(1)(iii)

without modification.

In contrast to verbal conversations—which may vary in specificity, be subject to misinterpretation, or lack comprehensive documentation—electronic or mailed notices ensure that IOTA waitlist patients who are Medicare beneficiaries receive uniform, essential information in a format that permits review, retention, and dissemination to family members or other caregivers. This consideration is of particular significance with respect to a change in waitlist status from active to inactive, which directly affects a patient's eligibility to receive transplant organ offers. Additionally, written communication strengthens the documentation maintained within the medical record, thereby demonstrating that the IOTA participant has met the notification requirement to inform IOTA waitlist patients who are Medicare beneficiaries when their waitlist status changes from active to inactive. We also believe that providing change in waitlist status notifications electronically or by mail can also mitigate the risk of miscommunication or disputes by providing a clear, time-stamped record of notification, while permitting transplant teams to conduct subsequent discussions to address questions or provide additional support. In this manner, written communication serves as the primary method for conveying critical information, while verbal interactions remain a valuable supplement rather than the sole means of notification.

Furthermore, we note with significant concern that an approach reliant upon verbal notification could impose significant operational challenges and administrative burden, particularly upon IOTA participants maintaining large waitlists or operating with limited staffing resources, and may result in delayed notification in circumstances where IOTA patients who are Medicare beneficiaries cannot be reached in a timely manner. We also note that the policy does not preclude IOTA participants from engaging in additional patient-centered communication, including direct discussions. In this manner, written communication serves as the primary method for conveying critical information, while verbal interactions remain a valuable supplement rather than the sole means of notification.

Comment: A commenter strongly supported the proposal to require notification to the patient, nephrologist, and dialysis center within 10 days of a change in waitlist status. The commenter further recommended that all status changes be formally documented and made visible in the patient's EHR portal to promote transparency and accessibility. The commenter emphasized that patients should be clearly informed when their status changes, the effective date of the change, the reason for inactivation, and the specific steps necessary to regain active status. According to the commenter, because waitlist status directly affects a patient's eligibility to receive organ offers, failure to provide timely and clear notification may result in patients later discovering that they spent time inactive without their knowledge, which can cause significant distress and undermine trust in the transplant process.

Response: We thank the commenter for their support of the proposal to require notification to the patient, nephrologist, and dialysis facility within 10 days of a change in waitlist status from active to inactive. We agree that timely and clear communication regarding waitlist status is critical because inactive status directly affects a patient's eligibility to receive kidney transplant organ offers. We also appreciate the commenter's recommendation that status changes be documented and visible through a patient's EHR portal to promote transparency and accessibility. We believe the change in waitlist status documentation requirements promote accountability and provide a clear record that the patient was informed of the change in status, the effective date of the change, and the steps necessary to regain active status. While the regulation does not mandate a specific technological platform, such as an EHR portal, IOTA participants retain flexibility to use existing electronic systems, including patient portals, to facilitate communication and patient access to this information.

We agree with the commenter that failure to provide timely and clear notification of inactive status could result in patients later discovering that they spent time inactive without their knowledge, which may cause distress and undermine trust in the transplant process. We note that change in waitlist status provisions is intended to reduce this risk by ensuring timely

notification, clear communication, and appropriate documentation when an IOTA waitlist patient who is a Medicare beneficiary's eligibility to receive kidney transplant organ offers is affected. Although we are finalizing these provisions without modification, as mentioned in comment responses noted previously in this section, we will take this comment into consideration for future notice and comment rulemaking.

Comment: Several commenters supported CMS's proposal to require IOTA participants hospitals to notify IOTA waitlist patients who are Medicare beneficiaries on its transplant waitlist within 10 days of a change in status from active to inactive. In particular, a few commenters stated that such status changes directly affect a patient's eligibility to receive organ offers and that learning after the fact that time was spent in inactive status can be deeply distressing and may have lasting effects on patient trust.

Response: We thank the commenters for their support.

Comment: A commenter agreed that providing patients with clear information about the duration of their time on the waitlist, their current active or inactive status is important and beneficial to patient care. However, the commenter raised concerns about requiring formal documentation of specific actions a patient must take to regain active status when a change in waitlist status occurs. The commenter cautioned that outlining detailed or fixed requirements in writing—such as a defined list of steps necessary for reactivation—could foster mistrust, particularly because waitlist eligibility is often influenced by clinical indicators that may change over time. The commenter expressed concern that presenting reactivation requirements as static targets may be misleading and could create the perception that expectations have been altered arbitrarily, when in fact adjustments are driven by the evolution of a patient's medical condition. The commenter further noted that these discussions are currently conducted in a personalized and supportive manner, and that formalizing them through written notifications could make the process appear impersonal or overly clinical, potentially undermining trust and open communication between patients and their care teams.

Response: We thank the commenter for recognizing the importance of providing patients with clear information about their waitlist status and duration on the waitlist. We also appreciate the concerns raised regarding the documentation of information about how a patient may regain active status and the potential for misunderstanding if such information is perceived as rigid or static.

We clarify that the proposed documentation requirements at § 512.442(d)(2) through (3) do not require IOTA participants to establish fixed or exhaustive lists of reactivation criteria, nor do they require IOTA participants to represent reactivation requirements as unchanging or guaranteed outcomes. Rather, the provision requires that the notification—and corresponding documentation in the medical record—include information on how the IOTA waitlist patient who is a Medicare beneficiary may become active again, which could include general or individualized next steps based on the patient's current clinical circumstances. We expect that such information will reflect the dynamic nature of transplant candidacy and will be communicated in a manner that acknowledges that clinical indicators, testing requirements, and eligibility considerations may evolve over time.

Furthermore, we do not believe that requiring documentation of the notification will undermine personalized communication. To the contrary, we believe that documenting that the patient was informed of their inactive status, the reason for the change, and the steps to pursue reactivation promotes transparency, continuity of care, and accountability. The requirement to maintain a copy of the notification, the method of delivery, and the date sent in the patient's medical record ensures that there is a clear record of communication, which may help prevent misunderstandings and support coordination among the transplant team, dialysis facility, nephrologist, or referring provider, as applicable. We do not believe that these documentation provisions preclude supportive, individualized conversations; rather, they complement them by ensuring that key information is clearly conveyed and recorded.

Lastly, we agree that discussions regarding reactivation are often nuanced and patient-

specific. We also note that the proposed provision preserves flexibility for IOTA participants to tailor communications to each patient's medical condition, literacy level, and communication needs. It does not require overly prescriptive or formulaic language, nor does it prevent IOTA participants from framing reactivation steps as contingent on ongoing clinical assessment. Instead, it establishes minimum documentation standards to ensure that IOTA waitlist patients who are Medicare beneficiaries are informed and that such communication is consistently recorded. For these reasons, we are finalizing our proposal without modification.

Comment: A few commenters stated that many transplant programs lack the administrative infrastructure and staffing necessary to manage communications with larger volumes of active waitlisted candidates. The commenters indicated that implementing the proposed requirements would likely require significant new costs and workflow changes and could create confusion rather than clarity for patients. The commenters further suggested that without clear guidance on communication methods, documentation standards, and compliance expectations, the requirements could overwhelm transplant hospitals, divert clinical resources, and potentially delay transplant care.

Response: We thank the commenters for their feedback regarding administrative capacity, staffing limitations, and potential operational impacts associated with implementing the proposed documentation requirements. We recognize that transplant hospitals vary in size, infrastructure, and available administrative resources. However, we respectfully disagree that the documentation requirements at § 512.442(d)(2) are likely to impose significant new costs, require substantial workflow redesign, or overwhelm IOTA participants. As described in the 2025 Proposed Rule at 90 FR 57620 and in this section of this final rule, the provision requires IOTA participants to maintain in the patient's medical record a copy of the notification provided to the IOTA waitlist patient who is a Medicare beneficiary, the method by which the notification was delivered, and the date the notification was sent. These elements are consistent with standard clinical documentation practices already commonly maintained within transplant

hospitals and electronic health record systems, and we anticipate that the majority of IOTA participants will be able to incorporate them into existing workflows without significant additional infrastructure or staffing requirements.

We further note that the regulation intentionally does not prescribe a specific format, template, communication platform, or operational workflow. Rather, the provision establishes a limited set of documentation elements while affording IOTA participants the flexibility to utilize existing communication and recordkeeping systems to satisfy the requirement, including electronic health records, patient portals, or established correspondence procedures. This approach is designed to provide clarity regarding compliance expectations while minimizing administrative burden and preserving the flexibility necessary for IOTA participants to tailor implementation to their respective operational capabilities.

We also respectfully disagree that the documentation requirements are likely to cause confusion among IOTA waitlist patients who are Medicare beneficiaries or delay the provision of kidney transplant care. To the contrary, documenting that such Medicare beneficiaries were notified of a change in waitlist status from active to inactive serves to ensure transparency, supports care coordination among the transplant team and other providers, and establishes a reliable record that the patient was informed when their eligibility to receive kidney transplant organ offers was affected. Clear and thorough documentation may also reduce downstream administrative burden by preventing misunderstandings regarding whether and when a patient was notified of a change in waitlist status. For these reasons, and those discussed in the comment responses noted previously in this section, we are finalizing the proposed change in waitlist status documentation requirements at § 512.442(d)(2) without modification.

Comment: A commenter supported promoting patient awareness of transplant waitlist status but raised concerns that the proposed structured notification requirements for status changes are overly rigid and do not reflect the dynamic and sometimes urgent nature of transplant medicine. The commenter stated that the proposal would introduce duplicative

documentation processes, require repeated outreach even when patients have already made informed decisions, and increase administrative tracking without meaningfully improving clinical care. The commenter recommended that CMS allow transplant programs greater flexibility in how status changes are communicated and documented, consistent with existing OPTN practices, rather than adopting new prescriptive requirements.

Response: We thank the commenter for supporting efforts to promote patient awareness of transplant waitlist status and for raising concerns regarding flexibility in the context of dynamic transplant care. We recognize that clinical circumstances can change rapidly and that communication with patients must remain responsive, individualized, and timely. However, we do not agree that the proposed documentation requirements at § 512.442(d)(2) through (3) are overly rigid or duplicative. As discussed previously in comment responses in this section, these provisions establish minimum standards to ensure that IOTA waitlist patients who are Medicare beneficiaries are consistently informed when their status changes from active to inactive and that this communication is documented in the medical record. The requirements are not intended to prescribe how clinical discussions occur or to replace personalized communication; rather, they complement existing practices by ensuring that key information—including the status change, the reason for inactivation, and steps toward reactivation—is clearly conveyed and recorded, thereby enhancing transparency and accountability while preserving flexibility.

We also do not believe the requirement introduces duplicative documentation processes. Transplant hospitals routinely document significant clinical communications, and the required elements—maintaining a copy of the notification, documenting the method and date of delivery, and notifying appropriate members of the patient's care team—are consistent with established medical recordkeeping and care coordination practices. The proposed change in waitlist status provision requires IOTA participants to provide notification electronically or by mail within 10 days of the status change and annually thereafter for as long as the Medicare beneficiary remains inactive (that is, 365 consecutive days). These requirements do not mandate unnecessary or

repeated outreach beyond the specified annual notification for prolonged inactivity; rather, they ensure that when a change in waitlist status occurs, there is a clear, consistent, and verifiable record that the Medicare beneficiary and relevant providers were informed in a timely manner.

With respect to flexibility and alignment with OPTN policies, the requirement specifies the method of delivery but does not prescribe a particular format, template, or communication platform. This approach allows IOTA participants to incorporate the notifications into existing workflows and communication practices, including patient portals, secure messaging, or mailed correspondence, consistent with operational capabilities and patient preferences. We disagree that the policy increases administrative tracking without meaningful clinical benefit; instead, clear documentation of the change in waitlist status notification enhances transparency, reduces the risk of prolonged unintended inactivity, supports continuity of care across providers, and provides an auditable record that Medicare beneficiaries were informed of material changes affecting their eligibility to receive kidney transplant organ offers. These objectives promote transparency, care coordination, and accountability while preserving flexibility and are central to the IOTA Model's goals of improving patient engagement and access to transplantation. Therefore, as stated previously in comment responses in this section, we are finalizing the proposed change in waitlist status documentation requirements at § 512.442(d)(2) through (3) without modification.

Comment: A few commenters generally supported the proposal and highlighted that, compared to the proposed OPTN policy, the proposed IOTA Model includes additional components that the commenter considered especially important. Specifically, a commenter emphasized the value of requiring that notifications include clear information about how a patient may regain active status on a waitlist and that concurrent notification be provided to the patient's dialysis facility and nephrologist. This commenter cautioned that without these additional elements, the notification risks becoming another message delivered through a patient portal that may go unread and fail to meaningfully engage patients.

At the same time, another commenter noted that a separate OPTN proposal currently under public comment would require notification to all waitlisted patients when their status changes from active to inactive and is seeking stakeholder input on appropriate communication methods. This commenter observed that the OPTN proposal does not include requirements to communicate and document the reason for the status change or the steps to regain active status and encouraged coordination to avoid inconsistencies between CMS and OPTN requirements.

Response: We thank the commenters for their support of the proposed change in waitlist status documentation requirements at § 512.442(d)(2) through (3) and for recognizing the importance of including additional elements—such as clear information on how a patient may regain active status and concurrent notification to the patient's dialysis facility and nephrologist—to enhance the effectiveness of waitlist status communications. We agree that these components are critical to ensuring that notifications are meaningful, actionable, and supportive of patient engagement rather than perfunctory messages that may be overlooked. Requiring that change in waitlist status notifications include the reason for the status change, the implications for kidney transplant organ offer eligibility, and steps toward reactivation, along with documentation of such communications in the patient's medical record and notification to relevant care team members, promotes transparency, care coordination, and continuity of care for IOTA waitlist patients who are Medicare beneficiaries.

We also acknowledge the commenters' observations regarding the related OPTN proposal and the importance of coordination to minimize inconsistencies. We recognize that the OPTN is considering policies that would require notification to all waitlisted patients when their status changes from active to inactive and that those policies may differ in scope and detail from the IOTA Model requirements. CMS has independent authority to establish requirements within the IOTA Model that support its goals of improving patient awareness, engagement, and care coordination for Medicare beneficiaries. The additional documentation and communication elements included in the IOTA Model are intended to complement, rather than conflict with,

OPTN policy by ensuring that affected patients receive clear, actionable information and that key members of the patient's care team are informed. We intend to continue to coordinate with HHS and the OPTN as policies evolve to promote alignment where appropriate and to reduce unnecessary duplication or burden on IOTA participants.

Comment: A commenter recommended that, for compliance purposes, CMS require that all required change in waitlist status notifications be documented in the patient's medical record. The commenter stated that notifications not recorded in the medical record should be considered not to have occurred and emphasized that documentation of the notification should be clearly visible in the patient's chart. The commenter further stressed that such documentation should be accessible to all relevant parties, including the patient, to ensure transparency and accountability.

Response: We appreciate the commenter's recommendation and agree that documenting waitlist status change notifications in the patient's medical record is an important compliance practice. We agree that clear, verifiable records of required notifications are essential to protecting patients and ensuring accountability. As described in this section of this final rule, we proposed change in waitlist status delivery documentation requirements at § 512.442(d)(2), which includes 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.

As described in comment responses noted previously, we are finalizing this provision without modification. Additionally, as described and finalized in section II.B.6 of this final rule, we are finalizing our proposal to include this transparency requirement as a monitoring activity in the IOTA Model. We direct readers to section II.B.6 of this final rule for further discussion on monitoring activities for transparency requirements included in the IOTA Model.

After consideration of public comments, for the reasons set forth in this rule, we are

finalizing the proposed change in waitlist status requirements at § 512.442(d) without modification. We will continue to assess the change in waitlist status provision for notifying 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 (that is, from active to inactive) in the IOTA Model and may address a new or updated policy pursuant to future notice and comment rulemaking.

b. Health Equity Plans

In the 2024 Final Rule (89 FR 96407), in response to comments[109], 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.

As stated in the 2025 Proposed Rule, 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 (90 FR 57621). 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 proposed to remove 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

109 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.

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 the 2025 Proposed Rule we proposed to remove the health equity plan provisions from § 512.446 (a)(1) through (7) (90 FR 57621). 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 proposed to remove all health equity provisions at § 512.446, we proposed to remove the definitions for health equity goals, health equity plan, health equity plan intervention strategy, and health equity plan performance measure at § 512.402. We proposed 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)[110] 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.

Subsequent to the publication of the 2025 Proposed Rule, we have found that we misstated in the preamble which definitions we were proposing to remove from the rule; we

110 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/*

clarify that actually we intend 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, as laid out in the 2025 Proposed Rule regulation text (90 FR 57631).

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

The following is a summary of the comments we received on all of the proposals related to health equity plans and our responses:

Comment: A commenter stated that the health equity plan provisions effectively require transplant hospitals to adopt race-conscious frameworks and incorporate racial, ethnic, and socioeconomic characteristics into performance planning and improvement strategies. The commenter asserted that even though submission of these plans was "voluntary" in the 2024 Final Rule, the substantive content required would pressure participants to engage in activities that could be construed as addressing racial or demographic disparities in a manner outside CMS's authority and inconsistent with statutes governing organ allocation.

Response: We thank the commenter for their input on this issue. In the 2024 Final Rule (89 FR 96405 through 96407), CMS finalized a voluntary framework under § 512.446(a) permitting IOTA participants to submit a health equity plan containing specified elements intended to support participant-level planning around patient access and transplant-related outcomes. As finalized, submission of a health equity plan was not required for participation in the IOTA Model and was not tied to payment adjustments under the final model design.

We reiterate that the IOTA Model does not modify organ allocation policies, which are governed by the Organ Procurement and Transplantation Network (OPTN) under 42 CFR part

121. Allocation and transplantation decisions must be made based on objective and measurable medical criteria consistent with the OPTN Final Rule at 42 CFR 121.8. Additionally, federal civil rights laws prohibit recipients of federal financial assistance from discriminating in their programs or activities on the basis of race, color, national origin, sex, age, or disability. Section 1557 of the Affordable Care Act, 42 U.S.C. 18116(a) (race, color, national origin, sex, age, or disability) (applicable to "health" programs or activities); Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq*. (race, color, or national origin); Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq*. (sex); the Age Discrimination Act of 1975, 42 U.S.C. 6101, *et seq*. (age); Section 504 of the Rehabilitation Act of 1973 (disability), 29 U.S.C. 794(a). These laws generally would apply to a recipient's federally funded organ transplantation programs and activities. A qualified individual with a disability who—with or without reasonable modifications or the provision of auxiliary aids and services—satisfies the essential eligibility requirements of an organ transplantation program may not be discriminated against on the basis of disability by an entity covered by Section 504 in its organ transplantation programs or activities.[111] In addition, the Americans with Disabilities Act(ADA) prohibits discrimination on the basis of disability by state and local governmental entities, Title II of the ADA, 42 U.S.C. 12131 *et seq*., and by private entities in public accommodations, Title III of the ADA, 42 U.S.C. 12181 *et seq*. Federal laws protecting conscience and religious freedom may also apply. *See example*. the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq*.

We also note that this commenter raised other concerns about the IOTA Model, not directly related to the proposed removal of the health equity plan provision. The commenter raised concerns that CMS lacks the authority to make the model mandatory. CMS addressed this issue in the 2024 Final Rule at (89 FR 96304) where we pointed out that Section 1115A of the

111 See 29 U.S.C. 794 and implementing regulation at 45 CFR 84.56 (providing certain general and specific prohibitions on denying or limiting medical treatment, including organ transplants, based on disability); see also "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance," 89 FR 40066, 40088 (May 9, 2024).

Act and the Secretary's authority to operate the Medicare program authorize us to finalize mandatory participation in the IOTA Model for the selected IOTA participants. The statute does not require that models be voluntary or be tested first as a voluntary model, but rather gives the Secretary discretion to design and test models that meet certain requirements as to spending and quality. CMS chose to make participation in the IOTA Model mandatory for the selected kidney transplant hospitals to avoid the selection bias inherent to any model in which providers may choose whether or not to participate. Such a design will ensure sufficient participation of kidney transplant hospitals, which is necessary to obtain a diverse, representative sample of hospitals that will allow a statistically robust test of the model.

Additionally, the same commenter raised concerns about a May 2025 letter issued by HRSA around concerns related to activities by an OPO. HHS takes the allegations against the OPO very seriously and has responded using its regulatory authority. On May 28, 2025, HRSA issued a corrective action plan to the OPTN, which directed the OPTN to take a series of actions to address identified unsafe organ procurement practices[112]. Additionally, in September 2025, HRSA wrote a letter[113] directing the OPTN to require each OPO to designate a patient safety officer, whose role is to monitor and investigate patient safety events in real time. HHS is focused on combatting unsafe activities using its authority through CMS and HRSA. In September 2025, HHS also decertified an OPO for the first time, citing years of unsafe practices.[114] Given this regulatory effort to ensure patient safety, CMS is confident in continuing to test the IOTA Model, subject to the monitoring provisions laid out in § 512.462.

The commenter also raised concerns about how CMS would monitor utilization of health

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112 Health Resources and Services Administration. (2025, March 24). *Information memo to the Associate Administrator:* HRSA-directed investigation into KYDA. https://d1dth6e84htgma.cloudfront.net/Attachment_1_Information_Memo_to_the_Associate_Administrator_KYDA_8939df6443.pdf

113 Health Resources and Services Administration. (2025, September 18). *Letter to the Organ Procurement and Transplantation Network regarding patient safety officer requirements*. https://www.hrsa.gov/sites/default/files/hrsa/optn/9182025-letter-to-optn-re-patient-safety-officer-requirements.pdf

114 U.S. Department of Health and Human Services. (2025, September 18). *HHS decertifies Miami organ agency, reforms transplant system*. https://www.hhs.gov/press-room/hhs-decertifies-miami-organ-agency-reforms-transplant-system.html

equity plans to ensure compliance with federal civil rights law. CMS never shared guidance with IOTA participants about how to create a health equity plan and did not receive any proposed health equity plans from IOTA participants. CMS reminds the public about the monitoring and compliance provisions in § 512.462(a) requiring compliance with all applicable laws and regulations and in § 512.462(b)(2) laying out a series of potential monitoring activities that CMS may use to determine if IOTA participants are complying with the requirements of the IOTA Model In addition, CMS reminds IOTA participants that they are separately required to comply with applicable federal civil rights laws, described above, independent of their obligations under CMS requirements.

For these reasons and current Administration priorities, we are finalizing the removal of § 512.446(a)(1) through (7) and the corresponding definitions at § 512.402 without modification.

Comment: Commenters contended that the voluntary nature of the health equity plans did not sufficiently limit legal exposure or administrative burden, asserting that voluntary provisions can create implicit incentives or pressures on participants to conform. Commenters maintained that requiring participants to prepare and submit detailed analyses of performance measures, goals, intervention strategies, and resource gap analyses—even on a voluntary basis—would consume significant participant resources and detract from primary model objectives. Commenters recommended removing the voluntary health equity plan provisions to eliminate these potential burdens.

Response: We appreciate commenters' support for the proposal. As discussed in the 2025 Proposed Rule, we recognize that even voluntary reporting structures may require significant planning, documentation, and administrative effort. We continue to believe that reducing unnecessary administrative burden is appropriate within a mandatory model, particularly where participants must focus resources on performance improvement and transplant access initiatives. For these reasons, we are finalizing the removal of the health equity plan provisions at § 512.446(a)(1) through (7) and the corresponding definitions at § 512.402 without

modification.

Comment: Some commenters supported eliminating the standalone health equity plan requirement but encouraged CMS to ensure that equity-related considerations remain embedded in transplant system oversight. These commenters suggested that equity efforts could be incorporated into existing OPTN processes, quality improvement structures, or broader transplant performance activities rather than through a separate IOTA-specific health equity plan.

Response: We appreciate commenters' recommendation to integrate patient-centered and access-focused considerations through existing frameworks. We note that organ allocation and transplant oversight are governed through the OPTN under 42 CFR part 121, and nothing in this rule alters those requirements. The removal of the IOTA-specific health equity plan provisions does not preclude transplant programs from continuing to engage in quality improvement efforts addressing access or patient needs under existing regulatory and clinical frameworks. In undertaking such quality improvement efforts addressing access or patient needs, transplant programs should be mindful of their obligations under federal civil rights laws which prohibit recipients of federal financial assistance from discriminating in their programs or activities on the basis of race, color, national origin, sex, age, or disability. We will continue to evaluate opportunities, through future notice and comment rulemaking if appropriate, to support improvements in access consistent with statutory authority and current Administration priorities.

Comment: Several commenters opposed CMS's proposal to remove the voluntary health equity plan provisions. These commenters stated that disparities in transplant referral, waitlisting, and transplantation rates persist across geographic regions and patient populations. Commenters asserted that eliminating health equity plans could signal reduced attention to disparities and recommended that equity remain a core component of the IOTA Model. Some commenters suggested that future iterations of the model include incentives or structured requirements to address persistent differences in transplant access.

Response: We acknowledge commenters' concerns regarding disparities in transplant

access and patient outcomes. We continue to maintain that improving access to kidney transplantation for all eligible patients is central to the IOTA Model's goals. However, after considering public comments and current Administration priorities, we believe that removing the voluntary health equity plan provisions is appropriate to reduce administrative burden and ensure participant focus on the model's core objective of increasing transplant volume and improving quality of care. The removal of these provisions does not prevent transplant hospitals from continuing to address barriers to care or engage in patient-centered improvement activities under existing authorities, subject to the anti-discrimination provisions in federal civil rights law outlined above. CMS may consider additional policy approaches in future rulemaking consistent with statutory authority and Administration priorities.

Comment: Some commenters expressed concern that eliminating the health equity plan provisions entirely, rather than modifying or streamlining them, may reduce systematic attention to disparities in access, referral patterns, and patient engagement. Commenters suggested that CMS consider alternative approaches, such as simplified reporting or integration of disparity-related measures into broader model evaluation, rather than complete removal.

Response: We appreciate commenters' suggestion to consider alternative approaches. At this time, we are finalizing removal of § 512.446(a)(1) through (7) and the associated definitions at § 512.402 in order to reduce administrative burden and align the model with current priorities. We note that the IOTA Model continues to include achievement, efficiency, and quality domains designed to improve kidney transplant access and patient outcomes. CMS may consider future refinements to the model, including elements consistent with the Administration's MAHA initiative, through subsequent notice and comment rulemaking.

Comment: Some commenters emphasized that transplant allocation decisions should remain grounded in objective medical criteria established under the OPTN framework and expressed support for CMS's statement that allocation and transplantation decisions should not be based on race or other non-medical criteria.

Response: We agree that allocation decisions must be made in accordance with the OPTN framework and applicable regulations at § 121.8, which require that organ allocation policies be based on objective and measurable medical criteria. The removal of the health equity plan provisions reinforces that the IOTA Model does not alter or supersede existing allocation policies. We reiterate that nothing in the IOTA Model modifies the OPTN's authority related to allocation policy or clinical decision-making.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing our proposed provision to remove the health equity plan provisions from § 512.446(a)(1) through (7), without modification. We are also finalizing our proposals to remove the definitions for health equity goal, health equity plan, health equity plan intervention strategy, health equity plan performance measure, resource gap analysis, target health disparities, and underserved communities at § 512.402 without modification.

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, in the 2025 Proposed Rule (90 FR 57621), we proposed to update the policy at § 512.450(a)(1) to limit these notification requirements to Medicare beneficiaries only.

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

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters expressed support for the proposed modifications to limit notification requirements to Medicare beneficiaries, with a few commenters asking for

clarification whether this proposal would be for Medicare FFS beneficiaries, MA beneficiaries, or both.

Response: We thank the commenters for their support. The modifications in the 2025 Proposed Rule are applicable to all Medicare beneficiaries, including those in both Medicare FFS and MA.

Comment: A few commenters expressed concern for the proposed modifications to limit notification requirements to Medicare beneficiaries as changes driven by IOTA participation affect all patients regardless of insurance, IOTA participants must communicate transparently with all patients whose outcomes affect model performance, and Medicare eligibility is often unclear at the time of transplant.

Response: We appreciate the commenters' concerns regarding limiting communications to Medicare beneficiaries. We have carefully considered these comments and would like to clarify that in the IOTA Model CMS only has the authority to require these notifications to be provided to Medicare beneficiaries. However, this does not preclude an IOTA participant from providing notifications to all attributed patients.

After consideration of the public comments we received, we are finalizing our proposed provisions for limiting beneficiary notification requirements to Medicare beneficiaries at § 512.450(a)(1) without modification.

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 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 proposed 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 had affirmatively opted out of receiving paper communication and had chosen to receive communication through electronic methods, this notification could be distributed through that agreed upon electronic method.

We sought 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 had affirmatively opted out of receiving paper communications.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters expressed support for the proposed modifications to allow IOTA participants to deliver beneficiary notifications electronically, with a few commenters suggesting that electronic delivery be the default method, requiring patients to opt-out of receiving electronic communication rather than opt-in for such receipt.

Response: We thank the commenters for their support. We understand that some electronic health record systems use code functionality for electronic notifications around opt-ins and not opt-outs. As such, we are finalizing our proposal at § 512.450(a)(3)(iii)(A) and (B) to allow the distribution of beneficiary notifications in an electronic format with modification. Specifically, we are modifying § 512.450(a)(3)(iii)(A) to specify electronic formats may be used if the attributed patient has affirmatively opted out of receiving paper communication or has chosen to receive communication through electronic methods.

Comment: A few commenters expressed concern with revisions to the beneficiary notification process, noting that the current process with notification has functioned effectively and ensures that all patients receive consistent information and have recommended keeping the

existing requirements.

Response: We thank the commenters for their feedback. Although CMS agrees that the current notification requirements ensure that beneficiaries receive consistent information, CMS believes that to ensure it remains adaptable to evolving technologies, a modification to the existing requirements can reduce unnecessary burdens while still preserving the safeguards afforded to beneficiaries.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions for allowing IOTA participants to distribute a paper notification to applicable attributed patients at the first in office or outpatient visit, or to distribute the notification in an electronic format at § 512.450(a)(3)(iii)(A) and (B), with a slight modification to allow an applicable attributed patient who has already chosen to receive electronic communications to continue to receive the notifications by that method. Accordingly, we are also modifying the regulation at § 512.450(a)(3)(iii)(B) to allow electronic communications to be sent to applicable attributed patients who affirmatively opt-out of receiving paper communication or who choose to accept electronic 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, as stated in the 2025 Proposed Rule (90 FR 57622), we inadvertently omitted monitoring of the transparency requirements specified in § 512.442. These included—

- 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 final

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

The following is a summary of the comments received on the proposed requirements at proposed § 512.462(b)(2)(xi), (xii), (xiii), and (xiv) and our responses:

Comment: CMS received several questions from commenters asking for clarification on the overall monitoring structure, including the types of monitoring to be conducted, monitoring frequency, and how compliance will be assessed in relation to existing regulatory and reporting requirements.

Response: We thank the commenters for their questions. 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). In recognition that we inadvertently omitted monitoring of the transparency requirements specified in § 512.442, we proposed to include those in the 2025 Proposed Rule, as described in this section of this final rule. As set forth in § 512.462(b)(1) and as described in the 2024 Final Rule (89 FR 96429), CMS may conduct monitoring activities to "ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model." Section § 512.462(b)(2) provides examples of the types of monitoring activities that may occur. We note that the overall

monitoring structure, as well as the frequency and how compliance will be assessed in the IOTA Model will be determined by CMS and may depend on the particular issue involved.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing, as proposed, the provision at § 512.462(b)(2)(xi), without modification. Since we are not finalizing the proposed transparency into kidney transplant organ offers requirement at this time, we are modifying our regulation at § 512.462(b)(2)(xii) through (xiv). Specifically, we are redesignating what was proposed at § 512.462(b)(2)(xiii) to be § 512.462(b)(2)(xii). We are also redesignating what was proposed at § 512.462(b)(2)(xiv) to be § 512.462(b)(2)(xiii).

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 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 (90 FR 57622). Therefore, we proposed 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,[115] OPTN's Management and Membership

115 For current OPTN policies please see https://www.hrsa.gov/optn/policies-bylaws

policies,[116] or HHS regulations (42 CFR part 121) upon a review conducted pursuant to 42 CFR 121.10. We also proposed 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 sought 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 sought comment on our minor technical corrections at proposed § 512.466(a)(3)(ix)(A) and (B).

The following is a summary of the comments received 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, on our minor technical corrections at proposed § 512.466(a)(3)(ix)(A) and (B) and our responses:

Comment: Several commenters expressed support for the proposed modifications as outlined in the 2025 Proposed Rule and this section of this final rule.

Response: We thank the commenters for their support regarding the proposed change that gives CMS the authority to 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 HHS regulations (42 CFR part 121) upon a review conducted pursuant to 42 CFR 121.10.

Comment: A commenter requested additional guidance on how CMS would operationalize the proposed authority, including due process protections, opportunities for corrective action, and alignment with existing OPTN enforcement mechanisms.

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

Response: We thank the commenter for their question. CMS will not intervene in, nor seek to influence, the OPTN's enforcement process. However, CMS may consider a determination made by OPTN or HHS regarding an IOTA participant's violation of OPTN's policies, OPTN's Management and Membership policies, or HHS regulations (42 CFR part 121) upon a review conducted pursuant to 42 CFR 121.10 as a basis for CMS to initiate termination proceedings from the IOTA Model under § 512.466(a)(3)(ix)(C).

Comment: A few commenters expressed opposition for giving CMS the authority to terminate an IOTA participant from the IOTA Model if HHS or the OPTN determined that an IOTA participant has violated the OPTN's policies and/or OPTN's Management and Membership policies.

Response: We thank the commenters for their comment and recognize the concerns raised regarding the scope of CMS's authority to terminate IOTA Model participants based on OPTN policy violations. We have carefully considered these comments and would like to reiterate the rationale for the proposed authority and how it complements existing oversight mechanisms. CMS has a statutory responsibility to ensure that Medicare beneficiaries receive safe, high-quality care and that Medicare funds are appropriately spent. CMS's proposed authority to terminate participants for OPTN policy violations is essential for several reasons. OPTN policy violations can directly impact patient safety and quality of care. As the payer for services under the IOTA Model, CMS must ensure that Medicare funds are only directed to IOTA participants who comply with all applicable requirements, including OPTN policies that govern transplant operations. The success of the IOTA Model depends on participant compliance with all applicable standards.

After consideration of the public comments we received, we are finalizing our policy in our regulation at § 512.466(a)(3)(ix)(C) as proposed but with a minor technical correction. Specifically, at § 512.466(a)(3)(ix)(C) we are changing "the HHS regulation (42 CFR 121)" to "HHS regulations (42 CFR part 121)". Additionally, we did not receive any comments on our

minor technical corrections at proposed § 512.466(a)(3)(ix)(A) and (B) and therefore are finalizing these provisions without modification.

8. Technical Corrections

In the 2024 Final Rule, we finalized our methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant at § 512.414(b)(3), as proposed without modification (89 FR 96319). This final rule corrects an error in the regulatory text at § 512.414(b)(3)(A) through (D) that was inadvertently not proposed in the 2025 Proposed Rule. Specifically, we are redesignating paragraphs § 512.414(b)(3)(A) through (D) as paragraphs § 512.414(b)(3)(i) through (iv). This does not change the meaning of any of the text.

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

In the 2025 Proposed Rule (90 FR 57622), we sought input on several requests for information (RFIs).

1. Pre-transplantation Access Process Measure

In the proposed rule (90 FR 57623), we sought comment on the potential use of pre-transplantation access process measures in the IOTA Model. Specifically, we sought feedback on the following questions:

- 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 in this final rule, we intend to use this input to inform any future quality measure efforts, as appropriate.

2. Allocation Out-of-sequence (AOOS)

In the 2025 Proposed Rule (90 FR 57623), we sought comment on how CMS should account for, monitor, and provide transparency around the use of AOOS in transplant performance measurement and patient notification in the IOTA Model. Specifically, we sought feedback 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 occurrence and how does that align with the organ offer transparency provisions described elsewhere in this final 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 in this final rule, we intend to use this input to inform any future quality measure or CMS policy efforts, as appropriate.

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 final 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 aims to increase access to life-saving kidney transplants for patients

living with ESRD by incentivizing kidney transplant hospitals (that is, IOTA participants) to improve their care delivery capabilities and efficiency, as well as supporting greater care coordination and person-centeredness in the organ transplant waitlist process. This 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.

This final rule finalizes the inclusion of MA beneficiaries in the definition of Medicare kidney transplants while keeping the maximum upside risk payment at $15,000. This final rule also updates the scoring on the composite graft survival rate.

B. Overall Impact

We have examined the impacts of this final 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 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 final rule was reviewed by the Office of Management and Budget.

C. Detailed Economic Analysis

1. Policy Changes Modeled by Rule

Table 12 summarizes the policy changes modeled for each version of the rule. Starting with the 2025 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. The projected impact of the inclusion of MA beneficiaries in the definition of Medicare kidney transplants was first modeled in the 2025 Proposed Rule as an alternative considered and is being finalized in this 2026 Final Rule. The inclusion of MA beneficiaries in the definition of Medicare kidney transplants allows for upside and downside risk payments to be calculated using the number of kidney transplants furnished to both beneficiaries of Medicare FFS and MA as primary or secondary payer. The inclusion of MA beneficiaries accounts for growth in MA, mitigates variation in geographic MA penetration, and increases savings to the Medicare trust fund. The 2025 Proposed Rule also projected the impact of decreasing the maximum upside risk payment from $15,000 to $10,000, as an alternative considered along with the inclusion of MA beneficiaries in the definition of

Medicare kidney transplants, but this 2026 Final Rule is not finalizing a reduction in the maximum upside risk payment.

TABLE 12: SUMMARY OF POLICY CHANGES MODELED BY RULE

	2024 Final Rule (89 FR 96440)	2025 Proposed Rule (90 FR 57626)	2025 Proposed Rule Alternative (90 FR 57628)	2026 Final Rule
Revised baseline	No	Yes	Yes	Yes
Include MA beneficiaries in the definition of Medicare kidney transplants	No	No	Yes	Yes
Maximum upside risk payment	$15,000	$15,000	$10,000	$15,000
Scoring on the composite graft survival rate	Original	Proposed	Proposed	Finalized

The original points allocation for the composite graft survival rate in the 2024 Final Rule had the potential to penalize kidney transplant hospitals that accept higher-risk kidney transplant patients. The proposed scoring in the 2025 Proposed Rule aimed to remove the possibility of getting free points for poor performance and provide a more even scoring distribution for participants. The 2026 Final Rule builds upon the scoring methodology in the 2025 Proposed Rule by increasing the number of possible scores from five to eight to remove the potential for large disparities among point distributions and align scoring with the achievement domain. Table D 13 illustrates the allocation of points awarded to IOTA participants for the composite graft survival rate in this final rule.

TABLE 13: COMPOSITE GRAFT SURVIVAL RATE SCORING 2026 FINAL RULE

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
87.5th percentile and above	Greater than or equal to 87.5th percentile	N/A	20
75th to below 87. 5th percentile	Greater than or equal to 75th percentile	Less than 87.5th percentile	18
62.5th to below 75th percentile	Greater than or equal to 62.5th percentile	Less than 75th percentile	15
50th to below 62.5th percentile	Greater than or equal to 50th percentile	Less than 62.5th percentile	13
37.5th to below 50th percentile	Greater than or equal to 37. 5th percentile	Less than 50th percentile	10
25th to below 37. 5th percentile	Greater than or equal to 25th percentile	Less than 37.5th percentile	8
12.5th to below 25th percentile	Greater than or equal to 12.5th percentile	Less than 25th percentile	5
Below 12.5th percentile	N/A	Less than 12.5th percentile	0

2. Projected Impact

As described in detail in the 2024 Final Rule, a stochastic model was constructed to estimate the financial impact of the IOTA Model. When possible, assumptions were informed by historical data. Transplant hospital adult transplant counts by donor type and recipients' primary

source of payment were obtained from the Scientific Registry of Transplant Recipients (SRTR) dashboard.[117] Organ offer acceptance ratios[118] and the composite graft survival rate[119] were analyzed from SRTR's program-specific statistics and transplant hospital-level data on kidney transplants. The SRTR data source includes data on all transplant donors, candidates, and recipients in the U.S.

IOTA participants receive upside or downside risk payments based on their performance across three domains: achievement, efficiency, and quality. The upside risk payment is a lump sum payment paid by CMS to the IOTA participants that achieve high final performance scores. Conversely, the downside risk payment is a lump sum payment paid to CMS by the IOTA participants with low final performance scores. The performance-based payments are based on the following thresholds. Total scores of 60 and above result in a maximum upside risk payment of $15,000, 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. Scores below 60 fall into the neutral zone with no upside or downside risk payment in PY 1. After the first PY, scores from 41 to 59 fall in the neutral zone, and scores of 40 and below would receive a downside risk payment. The maximum downside risk payment in the model is $2,000. 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

[117] Scientific Registry of Transplant Recipients. Adult Recipient Transplants By Donor Type, Center: U.S. Transplants Performed: January 1, 1988–September 30, 2024; For Organ = Kidney; Include: Transplant Year & Recipient Primary Source of Payment. https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/ . Accessed October 22, 2024.
[118] Scientific Registry of Transplant Recipients. National Center Level Data by Organ: Kidney CSRS Final Tables, Table B11 & Figures B10–B14. https://www.srtr.org/reports/program-specific-reports/. Accessed May 25, 2023.
[119] Scientific Registry of Transplant Recipients. National Center Level Data by Organ: Kidney CSRS Final Tables, Tables C5–C12 Figures C1–C20. https://www.srtr.org/reports/program-specificreports/. Accessed May 25, 2023.

total number of Medicare kidney transplants performed by the IOTA participant during the relevant PY.

We applied assumptions for transplant growth and performance on other domains affecting the incentive formula for included transplant hospitals for purposes of estimating impacts in this portion of the rule. Random variables accounted for variation in transplant growth and transplant hospital-level performance on other measures. A pivotal uncertainty relates to the potential growth in transplants as a result of upside and downside risk payments presented by the model. The current share of deceased donated kidneys that are discarded is roughly 20 percent.[120,121] Such growth was assumed to phase in over a 2- to 5-year period using a skewed distribution, with a gradual phase-in of 5 years being the most likely outcome.

Table 14 shows the projected impacts for upside and downside risk payments, transplants, and Federal spending in the 2026 Final Rule. In the final rule, we are maintaining the revised baseline, including MA beneficiaries in the definition of Medicare kidney transplants, keeping the maximum upside risk payment at $15,000, and applying the finalized scoring on the composite graft survival rate (Table 13). Transplant recipients with any type of insurance may benefit from a kidney transplant hospital's participation in the model. Model payments in this final rule are based on the number of transplant recipients who are beneficiaries with Medicare FFS or MA coverage including beneficiaries with Medicare as a secondary payer. Roughly 30 percent of IOTA participants are projected to receive upside risk payments in the first year (PY 1), rising to about 38 percent over the succeeding 5 PYs, with fewer than 24 percent of IOTA participants projected to owe downside risk payments in any of PYs 2 through 6. The magnitude of the average downside risk payment is relatively small, and the cumulative projected upside

[120] Li MT, King KL, Husain SA, et al. 2021. ''Deceased Donor Kidneys Utilization and Discard Rates During COVID–19 Pandemic in the United States.'' Kidney Int Rep; 6(9): 2463–2467. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8419126/.
[121] Robinson A, Booker S, Gauntt K, UNOS Research Department. 2022. ''Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report.'' OPTN Kidney Transplantation Descriptive Data Report. https://optn.transplant.hrsa.gov/media/p2oc3ada/data report_kidney_full_20220624_1.pdf.

risk payments to IOTA participants, amounting to $135 million, are nearly 45 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 77 percent of simulation trials. Therefore, in approximately 23% (100%-77%) of the 10,000 simulation trials for the IOTA Model, the projected net cost of payments will exceed the projected savings from new kidney transplants. The projected costs for those simulation trials range from $1 M to $310 M with a mean of $58 M and a median of $45 M over the 6-year model period. In Table 14, the mean 4,766 added transplants over the 6-year model period represents the number of new deceased or living donor transplants performed by IOTA participants for transplant recipients with any type of insurance. Overall, mean net savings totaled $88 million over 6 years, ranging from a savings of $246 million to a cost of $52 million at the 10th and 90th percentiles, respectively.

TABLE 14: PROJECTED IMPACT OF UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING 2026 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	16	20	23	26	24	26	135	104	168
Downside Risk Payments	0	-1	-1	-1	0	-1	-3	-4	-2
Total Net Payments	16	19	22	25	24	26	133	101	165
Added Transplants	208	442	704	986	1,184	1,243	4,766	2,055	7,708
Impact on Federal Spending	-8	-18	-31	-45	-57	-62	-221	-246	-78
Mean Net Savings	8	1	-8	-20	-33	-37	-88	-246	52

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

In Table D 14, 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).

3. Net Impact of Final Changes

In Table 15, we show the impact of the finalized changes on projected model outcomes, given by taking the finalized impacts in Table 14 less the proposed impacts from the 2025 Proposed Rule. The 2025 Proposed Rule illustrated the impact of a revised baseline, exclusion of MA beneficiaries in the definition of Medicare kidney transplants, a maximum upside risk payment of $15,000, and a proposed update to the scoring on the composite graft survival rate. The inclusion of MA beneficiaries is projected, on average, to result in marginally greater overall savings through additional growth in transplantation, because downstream savings (mainly through obviating the need for maintenance dialysis) are on average projected to ultimately exceed the elevated up-front expense for transplantation. This is offset by the finalized scoring methodology for the composite graft survival rate, which results in higher total upside risk payments due to the increase in the number of IOTA participants scoring in the upper percentile thresholds after the number of categories increased from five to eight. The range of uncertainty grew because the stakes are higher (greater potential savings from new transplants contrasted with greater incentive payouts). The model's net impact is projected to save nearly $38 million more in total over 6 years relative to the revised baseline.

TABLE 15: IMPACT OF FINAL RULE CHANGES: 2026 FINAL RULE LESS 2025 PROPOSED 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	7	9	10	11	11	12	60		
Downside Risk Payments	0	0	0	0	0	0	0		
Total Net Payments	7	9	10	11	11	12	60		
Added Transplants	71	150	240	340	412	432	1,644		
Impact on Federal Spending	-4	-8	-13	-20	-25	-28	-98		
Mean Net Savings	3	1	-4	-9	-14	-16	-38	-93	14

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

In Table 16, we show the impact of the finalized changes on projected model outcomes, given by taking the finalized impacts in Table 14 less the proposed impacts from the 2025 Proposed Rule Alternative. The 2025 Proposed Rule Alternative showed the impact of a revised

baseline, inclusion of MA beneficiaries in the definition of Medicare kidney transplants, a maximum upside risk payment of $10,000, and the original scoring methodology for the composite graft survival rate. The increase in the maximum upside risk payment from $10,000 to $15,000 and finalized scoring methodology for the composite graft survival rate are projected, on average, to result in a minor increase in costs. This is due to a 78 percent increase in net incentive payments largely offset by a 28 percent increase in gross savings. The model's net impact is projected to save approximately $10 million less in total over 6 years relative to the Proposed Rule Alternative.

TABLE 16: IMPACT OF FINAL RULE CHANGES: 2026 FINAL RULE LESS 2025 PROPOSED RULE ALTERNATIVE

							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	7	8	9	11	11	11	57		
Downside Risk Payments	0	0	0	0	0	0	2		
Total Net Payments	7	9	10	11	11	11	58		
Added Transplants	43	91	146	206	250	263	999		
Impact on Federal Spending	-2	-4	-7	-10	-13	-14	-49		
Mean Net Savings	5	5	3	1	-2	-2	10	-18	38

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

Finally, in Table 17, the difference is shown for the model as finalized in this final rule (from Table 14) relative to the baseline model specifications originally published in the 2024 Final Rule and re-estimated in the 2025 Proposed Rule.[122] This represents the estimated impact of this final rule in terms of the incremental changes for the various outcomes relative to what the model would have been expected to produce under the original finalized policies that would otherwise remain effective absent this new final rule. In Table 17, the mean 1,370 added transplants over the 6-year model period are due to the following reasons: (1) the inclusion of MA beneficiaries in the definition of Medicare kidney transplants; and (2) more IOTA participants were estimated to receive a positive incentive any given year because of the finalized scoring methodology for the composite graft survival rate, which results in higher total upside

[122] The baseline impact estimates from which the relative impacts are calculated can be found in 90 FR 57625, Table 4 of the 2025 Proposed Rule published on December 11, 2025.

risk payments due to the increase in the number of IOTA participants scoring in the upper percentile thresholds after the number of categories increased from five to eight.

TABLE 17: IMPACT OF FINAL RULE CHANGES: 2026 FINAL RULE LESS 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	5	6	7	5	6	32		
Downside Risk Payments	0	0	0	0	0	0	-1		
Total Net Payments	3	4	5	6	5	6	30		
Added Transplants	59	125	201	284	342	359	1,370		
Impact on Federal Spending	-3	-7	-12	-18	-23	-25	-89		
Mean Net Savings	0	-3	-7	-12	-18	-20	-59	-106	-15

4. 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 at least twice 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.[123,124] 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.[125] 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 be notified of a change in waitlist status. Using the same wage assumption noted previously, this would add $1,587 in cost per hospital [50 Medicare IOTA waitlist patients requiring a notification of a change in waitlist status x 0.25 hour per notification x $126.92 hourly wage]. Total estimated hospital cost per year is $7,933 per year [$6,346 + $1,587]. Therefore, the total cost would come out to $753,635 to complete the review of organ offer acceptance criteria for the 95 kidney transplant hospitals selected as IOTA participants [$7,933 × 95 IOTA participants = $753,635]. 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 $7,933 cost per IOTA participant to review the organ offer acceptance criteria would represent 0.4 percent [$7,933 / $2,000,000 = 0.4 percent] of their estimated total annual revenue from kidney transplants for Medicare beneficiaries.

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 final rule. We acknowledge that this assumption

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[123] Bureau of Labor Statistics (BLS). May 2024. "Occupational Employment and Wage Statistics." Accessed on March 30, 2026. *https://www.bls.gov/oes/current/oes_nat.htm*

[124] The most recent publicly available BLS Occupational Employment and Wage Statistics data are for May 2024 as of March 2026.

[125] 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.*

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 final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule; and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought 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].[126] 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 $12,581.80 [$132.44 × 95 IOTA participants = $12,581.80]. Therefore, the $132.44 cost per IOTA participant to complete the regulatory review would represent approximately 0.007 percent [$132.44/$2,000,000 = 0.007%] of their estimated total annual revenue from kidney

[126] Bureau of Labor Statistics (BLS). May 2024. "Occupational Employment and Wage Statistics." Accessed on March 20, 2026. *https://www.bls.gov/oes/current/oes_nat.htm*

transplants for Medicare beneficiaries.

E. Accounting Statement and Table

Consistent with OMB Circular A-4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 18 showing the classification of the impact associated with the provisions of this final rule. Annualized estimates were determined from Table 17 Mean Net Savings, and the 10th and 90th percentiles from the same table for determining the minimum and maximum estimates. Not reported in Table 18 is the estimated one-time total cost of the regulatory review of $33,772.20, which includes the cost of reviewing the rule for all commenters ($21,190.40) plus the cost of reviewing the rule for the IOTA participants ($12,581.80). These costs were not included in Table 17 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.

TABLE 18: ACCOUNTING STATEMENT

Category	*Primary Estimate*	*Minimum Estimate*	*Maximum Estimate*	*Year Dollar*	*Discount Rate*	*Period Covered*	*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 IV.E. of this final rule Accounting Statement and Table						Section IV.D. Regulatory Review Cost Estimation
Annualized quantified, but unmonetized, costs	-14	-21	-7	2026	7%	2026-2031	RIA Table 17. Row: Impact on Federal Spending Note: Net Medicare benefit cost reduction from additional transplants.
Qualitative (unquantified) costs	-14	-22	-7	2026	3%	2026-2031	
TRANSFERS							
Annualized	5	3	7	2026	7%	2026-	RIA Table 17. Row:

monetized transfers: "on budget"						2031	Total Net Payments Note: Net incentives paid to participating kidney transplant hospitals.
	5	3	7	2026	3%	2026-2031	
From whom to whom?	From:		Federal Government	To:	Participating kidney transplant hospitals	To:	
Annualized monetized transfers: "on budget"							
From whom to whom?							

G. Regulatory Flexibility Act (RFA)

Overall, kidney transplants only represent a small fraction of the revenue IOTA participants make and even the largest per transplant downside risk payment of $2,000 would not represent a significant economic impact on small entities. 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 22 percent of IOTA participants projected to owe downside risk payments in any of years 3 through 6. By contrast, we project that $135 million in total upside risk payments would be made over 6 years to roughly 30 percent of IOTA participants in the first year, rising to about 37 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 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 final 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, $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, 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. The total estimated average total burden per hospital of $8,065 would only represent 3 percent or more of total annual hospital revenue if total annual hospital revenue were less or equal to about $269,000. However, it would not be possible for a transplant hospital meeting the minimum 15 kidney transplants per year to have revenue low enough to approach such minimum threshold. Based on these estimates, we do not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary has certified that this final 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 604 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 final 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 final 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. The threshold in 2026 is approximately $193 million, reported in 2025 dollars. This final rule does not require spending above the threshold.

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 final 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. This rule is an E.O. 14192 deregulatory action, generating $4 million in annualized net cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

List of Subjects

42 CFR Part 512

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

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 28, 2026.

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

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

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. Removing the definitions for "Health equity goals," "Health equity plan intervention," "Health equity plan performance measure(s)," and "Health equity project plan";

b. Adding the definition for "MA";

c. Revising the definition for "Medicare kidney transplant";

d. Adding the definitions for "Military medical treatment facility," "MPSC", and PRA;

e. Removing the definition for "Resource gap analysis";

f. Adding the definition for "Single-organ kidney transplant";

g. Removing the definition for "Target health disparities";

h. Adding the definition for "Transplant organ offer acceptance criteria";

i. Removing the definition for "Underserved communities"; and

j. Adding definition for "VA medical facility".

The additions and revisions read as follows:

§ 512.402 Definitions.

* * * * *

MA stands for Medicare Advantage.

* * * * *

Medicare kidney transplant means a kidney transplant furnished to an attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS) or MA, as identified in Medicare FFS claims with MS-DRGs 008, 019, 650, 651, and 652, or

through OPTN data.

* * * * *

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 an MTF or VA medical facility as defined at § 512.402.

* * * * *

§ 512.414 [Amended]

4. Section 512.414 is amended by redesignating paragraphs (b)(3)(A) through (D) as paragraphs (b)(3)(i) through (iv)

5. Section 512.428 is amended by—

a. Revising paragraphs (b)(1)(ii), (b)(1)(iii)(E), and (b)(1)(iv)(A);

b. Adding paragraphs (b)(2) and (3);

c. Revising Table 1 to paragraph (d).

The revisions and additions read as follows:

§ 512.428 Quality domain.

* * * * *

(b) * * *

(1) * * *

(ii) For all subsequent PYs, CMS calculates the IOTA participant’s cumulative composite graft survival rate using the same calculation methodology described in paragraph (b)(1) of this section and in accordance with paragraph (b)(2) of this section.

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

* * * * *

(2) *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 using SRTR's adult kidney graft survival first-year outcomes variables in accordance with paragraphs (3)(i) through (iii) of this section.

(3) *Risk-adjustment methodology*--(i) *Calculation of Observed Composite Graft Survival Rate*. In accordance with paragraph (b)(1) of this section, CMS calculates the observed composite graft survival rate by dividing the number of functioning grafts plus two by the total number of completed kidney transplants plus two, as described in equation 2 to paragraph (b)(3)(i) of this section.

Equation **2** *to* **Paragraph** *(b)(3)(i): Observed Composite Graft Survival Rate Calculation.*

$$Composite\ Graft\ Survival\ Rate_{Observed} = \frac{\#\ of\ Functioning\ Grafts + 2}{\#\ of\ Completed\ Kidney\ Transplants + 2}$$

(ii) *Risk score calculation methodology*. CMS calculates a risk score for each IOTA participant as follows:

(A) *Expected graft failure rate Calculation.*

(*1*) CMS calculates the expected graft failure rate using SRTR's methodology as described in equation 3 to paragraph (b)(3)(ii)(A)(1).

Equation **3** *to* **Paragraph** *(b)(3)(ii)(A)(1): Expected Graft Failure Rate Calculation.*

$$Prob(failure) = 1 - S_0 t) exp^{(\beta X)}$$

(*2*) CMS uses both of the following:

(*i*) SRTR adult kidney graft survival first-year post-transplant risk-adjustment models for

both deceased donor and living donor kidney transplants.

(*ii*) SRTR's most available set of coefficients.

(B) *National graft failure rate calculation*. (*1*) CMS calculates the national graft failure rate by dividing the number of graft failures in a given PY by the number of completed kidney transplants in a given PY, as described in equation 4 to paragraph (b)(3)(ii)(B)(1) of this section.

Equation 4 to **Paragraph** *(b)(3)(ii)(B)(1): National Graft Failure Rate Calculation.*

$$National\ Graft\ Failure\ Rate\ = \frac{Number\ of\ Graft\ Failures}{Number\ of\ Completed\ Kidney\ Transplants}$$

(*2*) When calculating the national graft failure rate, CMS excludes all of the following:

(*i*) Patients who are under the age of 18 years of age at the time of the kidney transplant.

(*ii*) Pediatric kidney transplant hospitals as defined at § 512.402.

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

(*3*) In accordance with the provisions in paragraph (b)(3)(ii)(B)(2) of this section, CMS includes kidney transplant patients who have experienced any of the following in the numerator when calculating the national graft failure rate:

(*i*) Graft failure, based on OPTN adult kidney transplant recipient follow-up forms for all completed kidney transplants to determine failed grafts as defined by SRTR.

(*ii*) Re-transplant.

(*iii*) Death.

(*4*) When calculating the national graft failure rate, CMS only includes single-organ kidney transplants, as defined at § 512.402, and kidney/pancreas transplants for patients who are 18 years of age and older at the time of the kidney transplant in the number of kidney transplants performed during the given PY in the denominator.

(C) *Risk Score Calculation.* CMS calculates the risk score for each IOTA participant by dividing the amount resulting from the calculation in paragraph (b)(3)(ii)(A) by the amount resulting from the calculation in paragraph (b)(3)(ii)(B) as described in equation 5 to paragraph (b)(3)(ii)(C) of this section.

Equation 5 to **Paragraph** *(b)(3)(ii)(C): Risk Score Calculation.*

$$Risk\ Score = \frac{Expected\ Graft\ Failure\ Rate_{IOTA\ Participant}}{Graft\ Failure\ Rate_{National}}$$

(iii) *Risk-Adjusted Composite Graft Survival Rate Calculation*. CMS calculates the risk-adjusted composite graft survival rate for each IOTA participant by multiplying the amount resulting from the calculation in paragraph (b)(3)(i) of this section by the amount resulting from the calculation in paragraph (b)(3)(ii) of this section, as described in equation 6 to paragraph (b)(3)(iii) of this section.

Equation **6** *to* **Paragraph** *(b)(3)(iii): Risk-Adjusted Composite Graft Survival Rate Calculation*

$$Composite\ Graft\ Survival\ Rate_{Risk-Adjusted} = Composite\ Graft\ Survival\ Rate_{Observed}\ x\ Risk\ Score$$

* * * * *

(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
87.5th percentile	**Equals 87.5th percentile**	**Greater than 87.5th percentile**	**20**
75th percentile	**Equals 75th percentile**	**Less than 87.5th percentile**	**18**
62.5th percentile	**Equals 62.5th percentile**	**Less than 75th percentile**	**15**
50th percentile	**Equals 50th percentile**	**Less than 62.5th percentile**	**13**
37.5th percentile	**Equals 37.5th percentile**	**Less than 50th percentile**	**10**
25th percentile	**Equals 25th percentile**	**Less than 37.5th percentile**	**8**
12.5th percentile	**Equals 12.5th percentile**	**Less than 25th percentile**	**5**
12.5th percentile	**N/A**	**Less than 12.5th percentile**	**0**

6. 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 read as follows:

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

* * * * *

(d) * * *

(6) * * *

(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).

7. Section 512.436 is amended by revising paragraph (b) introductory text to read as follows:

§ 512.436 Extreme and uncontrollable circumstances.

* * * * *

(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:

* * * * *

8. Section 512.442 is amended by—

a. Revising paragraph (a);

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 to date on its website 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.

* * * * *

(c) * * *

(1) 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.

(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 (that is, from active to inactive).

(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]

9. Removing § 512.446.

10. 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) * * *

(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 IOTA Model; or

(B) If the applicable attributed patient has affirmatively opted out of receiving paper communication or 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.

* * * * *

11. Section 512.462 is amended by adding paragraph (b)(2)(xi) through (xiii) 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 review of acceptance criteria provision in accordance with § 512.442(c).

(xiii) Monitoring the change in waitlist status provision in accordance with § 512.442(d).

* * * * *

12. 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 regulations (42 CFR part 121) upon a review conducted under 42 CFR 121.10.

* * * * *

§ 512.470 [Amended]

13. Section 512.470 is amended by removing the phrase "and 1833(b) of the Act" and adding in its place the phrase "1833(b), and 1851(i)(2) of the Act, and 42 CFR 422.322(c)".

Robert F. Kennedy, Jr.

Secretary,

Department of Health and Human Services

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